Supreme Court, U.S.
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No.

IN THE

Supreme Court of the United States

MEDTRONIC SOFAMOR DANEK, INC., F/K/A/ SOFAMOR DANEK GROUP, INC., AND MEDTRONIC SOFAMOR DANEK USA, INC.,
Petitioners,

v.

DEPUY SPINE, INC. F/K/A DEPUY ACROMED, INC. AND BIEDERMANN MOTECH GMBH
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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April 27, 2007

QUESTION PRESENTED

This case presents a question of broad and general importance regarding patent infringement under 35 U.S.C. § 271: Has the Federal Circuit properly and consistently balanced the public notice function of patent claims (the goal of this Court's "all-elements rule") with the desire to protect patentees from unscrupulous copyists (the goal of the doctrine of equivalents)? If not, how can the analysis of patent infringement under the doctrine of equivalents be better crafted to achieve more consistent and predictable outcome?

The answer to this question can affect virtually every issued U.S. patent and every U.S. patent infringement action, as well as any enterprise and member of the public affected by the grant of a U.S. patent.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

Applicants Petitioners Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc., were defendants in the district court proceedings and cross-appellants in the court of appeals proceedings.

Respondents DePuy Spine, Inc. and Biedermann Motech GmbH were the plaintiffs in the district court proceedings and the appellants in the court of appeals proceedings.

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Petitioners Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic") respectfully submit this petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this action on November 20, 2006.

OPINIONS BELOW

The court of appeals' opinion is reported at 469 F.3d 1005 (2006) and is reproduced in Petitioner's Appendix ("App.") at 2a-34a.

The order denying Medtronic's petition for rehearing or rehearing *en banc* is unreported and is reproduced at App. 35a-36a. The Memorandum and Order of the United States District Court for the District of Massachusetts for Summary Judgment of Non-Infringement Concerning Medtronic's Vertex Screw is unreported and is reproduced at App. 40a-46a.

JURISDICTION

The district court had jurisdiction over respondent's claims pursuant to 28 U.S.C. § 1331 and 1338(a). The court of appeals had jurisdiction to review the district court's final judgment pursuant to 28 U.S.C. § 1295(a)(1). The court of appeals filed its opinion on November 20, 2006. That court denied Medtronic's timely petition for rehearing or rehearing *en banc* on December 28, 2006. On March 15, 2007, Chief Justice Roberts extended the time within which to file a petition for certiorari to April 30, 2007. No. 06A889. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Title 35 U.S.C.A. § 271(a) provides:

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

STATEMENT

This case concerns a defendant Petitioner, Medtronic, who was aware of a patent for a medical device (a spinal implant) having claims that specifically defined certain features of the device by their geometric shape. Medtronic attempted to "design around" the patent by building a device that, *inter alia,* used a different geometry for the relevant features of the device. The Federal Circuit had already decreed in a very similar case (that also involved a medical implant defined by its shape in the patent claim) that such a substitution removed the accused device from the reach of the doctrine of equivalents, basing its ruling on the so-called "all-elements rule." Nevertheless, in the present case the Federal Circuit declared that Medtronic's new device *could* in fact lie within the territory of an equivalent for the geometrically-defined claim element at issue. Medtronic was, not unreasonably, surprised by this contradiction. This petition implicates, however, more than this pair of contradictory decisions by the Federal Circuit; this petition concerns a string of decisions over the last decade that touch upon the "all-elements rule" and that have left patent owners and the public at large in great confusion over the scope of rights granted by patents.

The patent Medtronic had been accused of infringing claimed, among other things, a receiver chamber having "an inner hollow spherically-shaped portion," and a compression member for exerting a force such that a screw head "is pressed against the hollow spherically-shaped portion." U.S. Patent No. 5,207,678 ("678 patent"), col. 4, ll. 18-24. Medtronic wanted to "design around" this patent, a recognized action for those who wish to avoid infringement. *See, e.g., Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1457 (Fed. Cir. 1991). As a result, Medtronic's device had a *conically* shaped portion, not a *spherically*

shaped portion, against which the head of the bone screw pressed. In producing this device, Medtronic relied upon the public notice function of the clearly written patent claims, and this Court's holding in *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*, 520 U.S. 17, 29 (1997), which cautioned that "[i]t is important to ensure that the application of the doctrine [of equivalents], even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." That proscription for application of the doctrine of equivalents is known as the "all-elements rule." *See, e.g., Hughes Aircraft Co. v. United States*, 140 F.3d 1470, 1474 (Fed. Cir. 1998). Medtronic also relied on the Federal Circuit's decision in *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998), a case very similar to this case, in which the Federal Circuit found that a hemispherical shape could not infringe, under the doctrine of equivalents, a claim that called for an "essentially conical" shape because such infringement would violate the all-elements rule. However, the Federal Circuit's application of that rule has, as exemplified by this case, been woefully inconsistent.

The trial court in *DePuy AcroMed, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-10165-EFH (D. Mass. Feb. 24, 2004) ruled on summary judgment that the conically-shaped portion in Medtronic's device did not literally meet the "spherically-shaped portion" limitation recited in the '678 patent claims. (App. at 41a). The trial court also ruled that the conically-shaped portion of the accused device could not comprise an equivalent to the "spherically-shaped" limitation of the asserted claims without vitiating that claim limitation. (App. at 43a). The Federal Circuit reversed, finding that while there could be no literal infringement, there may be infringement by equivalents, and remanded for a trial on equivalence. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1019-1020 (2006) (App. at 33a).

In so doing, the Federal Circuit deprived Medtronic of its reasonable reliance on the words chosen by the patentee to define its patent rights and thereby created unnecessary uncertainty regarding how the public can determine the scope of a patentee's claimed invention.

The '678 patentees claimed only the specific "spherical" shape. Yet nothing in the record below suggests that the patentees could not reasonably have foreseen, when they applied for the patent, that by claiming their invention with a specific shape, devices that had a different shape would fall outside the boundaries of the claim. The Federal Circuit's decision in *DePuy Spine* allows the patentee to resort to the doctrine of equivalents to effectively rewrite the patent claim, which it could have drafted more broadly but did not.

Petitioner's experience demonstrates how the doctrine of equivalents, combined with erratic application of the all-elements rule, has made the scope of the patent right attaching to a specifically written claim unpredictable. The resulting failure of confidence in the public-notice function of claims, if not arrested, will inhibit competition and further innovation unless this Court provides guidance on the use of the all-elements rule as a limit on the doctrine of equivalents.

This case gives this Court a timely opportunity to address this ambiguity and confusion. The question this Court must resolve is one of paramount importance in today's patent law: how should the all-elements rule be used to control the application of the doctrine of equivalents? This Court stated In *Warner-Jenkinson* that the all-elements rule *should* be used to limit the application of the doctrine of equivalents, but in the past decade the Federal Circuit has not settled on *how* it should be used, and has produced a body of irreconcilable decisions through its inconsistent application

of the rule. As a result, neither the public, who must know the definite limits of a patent, nor patentees, who must be protected from copyists making insignificant changes, are served.

The doctrine of equivalents for claims not expressed in means-plus-function form[1] is court-made law that evolved to prevent "the unscrupulous copyist" from making "unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law." *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950). Equivalence may be determined using either a test for similarity of function, way, and result, or a test for "insubstantial differences." *Warner-Jenkinson*, 520 U.S. at 39-40. No matter what formulation is used, however, it is perilous to anyone other than the patentee to apply the doctrine of equivalents. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 727 (2002) ("by extending protection beyond the literal terms in a patent the doctrine of equivalents can create substantial uncertainty about where the patent monopoly ends."). The subjectivity of the "insubstantial differences" or "function-way-result" tests can be relieved, in some cases, by the use of certain rules which have been developed by the courts to limit the doctrine. These rules, when consistently followed, help facilitate the public-notice function of patent claims. The all-elements rule is one such potentially useful rule.

The *first* task in any analysis of infringement under the doctrine of equivalents—preceding any assessment of facts by the fact finder—should be a determination of

[1] Elements described in "means plus function" claims as "a means for . . . ." are the only claim elements statutorily granted the possibility of equivalents. *See* 35 U.S.C. § 112 ¶ 6.

whether an element is vitiated. If so, the inquiry can stop there and no further test is needed because "if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further *material* issue for the jury to resolve." *id.* at 39 (emphasis in original). The Federal Circuit has not, unfortunately, always honored the primacy of the all-elements rule as laid down in *Warner-Jenkinson.*

To overcome inconsistency in the application of the all-elements rule, Petitioner respectfully submits that the application of the doctrine of equivalents should be guided by a foreseeability test. That test would ask whether, at the time the applicant obtained its patent, it could have foreseen that a specifically recited claim limitation could be met by a different structure (or step or component) that does not literally meet the recited claim element. If so, then the applicant could have, and should have, crafted the patent claims more broadly. The applicant's failure to do so should preclude application of the doctrine of equivalents to that specifically recited claim element. If the alleged equivalent of the claim element was not foreseeable, e.g., it comprised later-developed technology not reasonably known prior to the presentation of the claim, then the patentee should be allowed recourse to the doctrine of equivalents as to that claim element, assuming no other limitation on the doctrine, such as prosecution history estoppel, applies.

STATEMENT OF THE CASE

DePuy Spine and Biedermann Motech accused Medtronic Sofamor Danek of infringing the '678 patent with its Vertex pedicle screw product. The '678 patent describes and claims an orthopedic implant, a pedicle screw that is free to pivot inside a receiver member prior to being locked at a chosen angle by the surgeon. To permit such pivoting (or polyaxial) movement, Claim 1 of the '678 patent calls for the screw to have a "spherically-shaped" head which fits within a "spherically-shaped" portion of a receiver member. These specific shapes are identified with reference numerals 4 and 9 in the patent drawings and in claim 1.

The relevant portion of Figure 1 of the '678 patent, and the Medtronic device, are shown below:

From '678 Patent – Figure 1

Medtronic's Vertex device

BEST AVAILABLE COPY

Claim 1 of the '678 patent recites:

> 1. Device for stabilizing spinal column segments, comprising a pedicle screw (1) having a threaded shaft portion (3) and a spherically-shaped head (4) at the end of said threaded shaft portion, a receiver member (5) flexibly connected to said head (4), said receiver member being provided with two holes for receiving a rod 916) [sic:(16)], a receiver chamber (7) being provided within said receiver member (5), the receiver chamber (7) having at one end thereof a bore (8) for passing the threaded shaft portion (3) there through and *an inner hollow spherically-shaped portion* (9) for receiving the head (4) of said screw (1), an opening (10) being provided opposite said bore (8) for inserting said screw (1), said device further comprising a compression member (18) for exerting a force onto said head (4) such that said head is pressed against *the hollow spherically-shaped portion* (9).

'678 patent, col. 4, ll. 9-24 (emphasis added). The emphasized phrases in claim 1 give rise to this dispute. In Medtronic's Vertex product, the interior portion of the receiver member adjacent to the screw head is conical, not spherically-shaped. *DePuy Spine,* 469 F.3d at 1011. Thus, the screw head in Medtronic's Vertex product cannot be pressed against "a hollow spherically-shaped portion."

After holding a hearing on claim construction the trial court construed the "spherically-shaped" limitation to mean "approximately spherical, such as a globe or basketball," *DePuy AcroMed, Inc. v. Medtronic Sofamor Danek, Inc.,* No. 01-10165-EFH (D. Mass. Oct. 27, 2003) (App. at 51a). The court then concluded that the Vertex product did not literally infringe the '678 patent, because it

contained no spherically-shaped portion in the receiver; rather, it had conical lower chamber walls. *DePuy AcroMed, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-10165-EFH (D. Mass. Feb. 24, 2004) (App. at 41a). The district court then invoked the all-elements rule to conclude that the Vertex screw did not infringe the '678 patent under the doctrine of equivalents because "the cylindrical-conical shape of the Vertex screw receiver member cannot infringe the '678 patent without reading out of the claim the express requirement that the screw head be 'pressed against the hollow, spherically-shaped portion'" of the receiver chamber. (App. at 43a-44a). The court also found that the Vertex screw did not infringe under the function/way/result test for equivalence because it "does not do 'substantially the same thing' as the screw disclosed in the '678 patent," in that the Vertex screw head contacts only an edge or lip of the receiver member rather than the larger area of the hollow spherically-shaped portion of the receiver chamber. (App. at 44a).

On appeal, DePuy challenged the district court's finding that no issue of material fact exists as to whether the Vertex product infringes the '678 patent, both literally and under the doctrine of equivalents. The Federal Circuit affirmed the grant of summary judgment of no literal infringement, finding that no evidence had been presented that the Vertex receiver member contained "a portion that meets the literal terms 'approximately spherical, such as a globe or basketball.'" *DePuy Spine*, 469 F.3d at 1016. However, the Federal Circuit reversed the grant of summary judgment under the doctrine of equivalents. Even though the patent claim unambiguously calls for a *spherically shaped* receiver member and Medtronic's accused product has a *conically* shaped receiver member, the Federal Circuit held that there *could* be infringement under the doctrine of equivalents, finding "no support . . . for the district court's

conclusion that applying the doctrine of equivalents would vitiate or read out the 'spherically-shaped' limitation." *Id.* at 1019. On remand, the Federal Circuit required the fact finder to determine "whether the difference in the [argued] equivalent is "substantial," *Id.* at 1021, and if those differences were *not* found to be "substantial," then infringement under the doctrine of equivalents *could* exist notwithstanding the "all-elements rule." *Id.*

In so subordinating application of this Court's all-elements rule to a test for substantial differences, the Federal Circuit's decision in *DePuy Spine* effectively negated the basis for that rule—to insure that every limitation in a patent claim be accounted for to thereby provide appropriate certainty to a patentee's scope of rights. Moreover, the Federal Circuit provided no guidance or test to determine when differences between a claim element and an accused equivalent structure rise to the level of "substantial" differences.

REASONS FOR GRANTING THE PETITION

I. This Case is One of Many That Illustrate the Uncertainty Generated By the Federal Circuit's Application of the All-Elements Rule and the Doctrine of Equivalents, Thus Establishing the Need for Further Guidance And Refinement of the Rule By This Court.

A. *DePuy Spine* Cannot be Distinguished From *Tronzo*, So The Decision in *DePuy Spine*, Which Directly Contradicts That in *Tronzo*, Demonstrates The Inconsistency In Federal Circuit Rulings

1. The Claims in Both *Tronzo* and *DePuy Spine* Unambiguously Call For a Specific Shape

The claim in question in Tronzo's patent recited a "body" of a prosthetic hip implant that had a "generally conical outer surface." U. S. Patent No. 4,743,262, col. 12, l. 9. The claim in question in *DePuy Spine* recites, *inter alia*, a receiver chamber *having an inner hollow spherically-shaped portion for receiving the head of the screw*, and a compression member for exerting a force onto the screw head "such that said [spherically-shaped screw] head *is pressed against the hollow spherically-shaped portion*." '678 patent, col. 4, ll. 9-24 (emphasis added). The claimed inventions in *Tronzo* and *DePuy Spine* both relate to a medical implant and unambiguously call for specific shapes: "generally conical" in *Tronzo*, and "spherically-shaped" in *DePuy Spine*. The accused devices in *Tronzo* had a hemispherical shape instead of the claimed conical shape, while the accused devices in *DePuy Spine* had a conical shape instead of the claimed spherical shape.

2. The Patents In Both *Tronzo* and *DePuy Spine* Make It Clear That The Claimed Shape Was The Preferred Shape

The Federal Circuit attempted to differentiate *DePuy Spine* from *Tronzo* on the basis that "unlike the patent at issue in Tronzo, the written description in the '678 patent does not label other shapes as 'prior art' and 'inferior.'" *DePuy Spine,* 469 F.3d at 1020. But the spherical shapes of the screw head and interior of the receiver chamber of the '678 patent—specific features of the invention—were not new. The inventors of the '678 patent combined these old elements with newer ones to form their invention. As such, the spherical shapes themselves did not have to be distinguished from the prior art. In fact, the '678 inventors freely acknowledged that "a very well-operating pedicle screw" was known from their own prior art reference EP 0 242 708, which describes and illustrates a pedicle screw with a spherically-shaped head connected to a spherically-shaped receiver, thereby "allowing a pivoting movement around the center of the hollow sphere . . . ." '678 patent, col. 1 ll. 44-45. The '678 invention was driven by the fact that, although the prior art screw was "well-operating," it had a drawback: "[w]hen using this known screw, it is necessary to have the entire screws [i.e., with receiver] in the desired sizes in stock. However, the stocking costs for such complete screws are very high. . . . " '678 patent, col. 1, ll. 47-50. The inventors of the '678 patent wanted to overcome this drawback, "to provide a possibility for reducing the stocking costs of such screws." '678 patent, col. 1 ll. 54-55. "Such screws" were the prior art spherically-headed screws with spherically-shaped receivers. Because the '678 patent inventors acknowledged and incorporated into their new design the prior art spherical shape, they did not have to show that the *shape* of their receiver was superior to shapes in the prior art. It was the *combination* of the remaining

elements of claim 1 with the known spherically-shaped receiver that produced a superior product.

The Federal Circuit's attempt to distinguish *Tronzo* from *DePuy Spine* on the basis of comments about the claimed shape in Tronzo's patent specification thus fails, because the *DePuy Spine* inventors specifically claimed the *same* shape for the receiver chamber as existed in the prior art and relied on different features to distinguish their invention. Moreover, nothing in the record suggests that it was not foreseeable to the '678 patentees that a different shape for the receiver chamber would also allow the screw to pivot within the receiver member. Thus, a specific shape for the receiver chamber was not necessary to distinguish the '678 claimed invention from the prior art, but the patentees nevertheless claimed their invention with that shape and should not now be permitted to effectively re-write the claim to cover different shapes.

3. Expert Testimony in Both *Tronzo* and *DePuy Spine* Indicated That Any Shape Would be Equivalent To the Claimed Shape, Thus Vitiating the Claim Element

The expert testimony in *Tronzo* was that "when either a hemispherical cup or trapezoidal cup or any other shape cup is successfully implanted into the body, it functions almost exactly the same way." *Tronzo*, 156 F.3d at 1160. In its *Tronzo* opinion, the Federal Circuit took this testimony to indicate that "any shape would be equivalent to the conical limitation of claims 2 and 10," and recognized that "[s]uch a result is impermissible under the all-elements rule. . . ." *Id.* at 1160.

As in *Tronzo*, the relevant expert testimony in *DePuy Spine* concerned the "function, way, and result" test of

equivalence. As in *Tronzo*, the patentee's expert in *DePuy Spine* testified that the specifically claimed shape was irrelevant. In response to the question of whether there is "any shape that the bottom portion of the receiver member can take that would not be an equivalent to the spherically-shaped portion as recited in claim one of the patents," this expert stated that:

> The issue as I have cited under the Doctrine of Equivalents, *the issue is not the shape of the bottom of the receiver. The issue is whether a bore in the bottom of the receiver contains the head of the screw.*
>
> It's too small to permit the head of the screw to pass; that the receiver has room for the head, and that the hole be such that it permits angulation, and it's a bore, it's rounds [sic], and therefore, that's the only requirement for angulation.

Deposition of Robert Mann, Sc.D., Dec. 20, 2002, p. 49. (emphasis added). In other words, the shape is irrelevant because (according to DePuy's theory of equivalence) the only requirements for the bottom portion of the receiver chamber were that it contain a bore through which the screw could pass; that this bore not be so large as to allow the head of the screw to pass through; and that the bore be round, to permit the screw to be fixed in any direction. The patentee's equivalence theory in *DePuy Spine* was, therefore, the same as that in *Tronzo*: *any* shape would be equivalent to the shape specifically called for in the claim, so long as the alleged function was achieved. Under this theory, the claimed "hollow spherically-shaped portion" of the '678 patent is eviscerated because only a "hollow portion" is necessary. A specific feature of that claim, the spherical shape of the hollow portion, has been discarded and that

claim element has been vitiated.[2]

The Federal Circuit attempted to differentiate its decision in *DePuy Spine* from *Tronzo*, and thus justify its diametrically opposite result, by pointing out factual differences between the cases, noting that "Tronzo is limited to the facts and theories of equivalence presented in that case," *DePuy Spine*, 469 F.3d at 1019, n.1. But the Federal Circuit has never criticized the *method of analysis* it used in *Tronzo*. Simply noting that a particular decision is limited to the facts presented in that case only emphasizes the lack of certainty and predictability in the Federal Circuit's application of the all-elements rule and the doctrine of equivalents. The opposite result reached in *Tronzo* and *DePuy Spine* on strikingly similar issues highlights the need for this Court's guidance on those issues.

[2] The Federal Circuit stated that DePuy Spine's "expert expressly identified certain shapes that were different from the accused device but would not be capable of supporting the screw head, allowing flexible movement, and creating a rigid lock when the compression member is engaged." *DePuy Spine*, 469 F.3d at 1020. This testimony is said to appear in a "particularized declaration" by DePuy's expert Dr. Mann. *Id.* at 1019. Medtronic is unable to find specific testimony by Dr. Mann to this effect. The record shows that Dr. Mann identified "[a] square, a cube, a hexagon, a polygon" as shapes that were "not spherically shaped as required by claim one of this patent," deposition of Robert Mann, Sc. D., Dec. 20, 2002, p.97, but did not state that any such shape would be incapable of supporting the screw head, allowing flexible movement, and creating a rigid lock when the compression member is engaged--the "function, way, and result" that DePuy Spine defined for the "spherically-shaped" claim limitation.

B. In Many Cases the Federal Circuit Has Taken the "Hard," Literal Approach to the All-Elements Rule That It Took in *Tronzo*

Tronzo is only one of several decisions in which the Federal Circuit elected to adhere to the specific wording of a claim—a "hard" approach to the doctrine of equivalents. In *Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, 291 F.3d 1317 (Fed. Cir. 2002), the claim element in question called for "[a] wellhead comprising . . . a workover port extending laterally through the wall of the spool tree *from between the two plugs*." *Id.* at 1319. (emphasis added). The accused device had a workover port above, not between, the two plugs. The Federal Circuit upheld a summary judgment of non-infringement because "the workover port in Kvaerner's accused device enters the wellhead assembly 'above' the two plugs, which cannot be equivalent to a connection 'between the two plugs.'" *Id.* at 1322. The Federal Circuit acknowledged the all-elements rule, recognizing that if it were to ignore the use of the word "between" in the claim, "we would vitiate that limitation and thereby run afoul of the all-limitations rule." *Id.* The Federal Circuit did not ask whether the difference in location of the workover port was "substantial."

This hard approach was similarly evident in *Durel Corp. v. Osram Sylvania, Inc.*, 256 F.3d 1298 (Fed. Cir. 2001). The claim element in question called for "encapsulated electroluminescent phosphor particles, each comprising a particle of . . . phosphor which is essentially completely encapsulated within a . . . continuous *metal oxide coating* . . ." *Id.* at 1301. (emphasis in original). The Federal Circuit construed "oxide coatings" as primarily comprising a binary compound or compounds "containing only metal cations and oxygen." *Id.* at 1305. The court found that the accused products "contain an additional

element, hydrogen, and therefore do not meet the claim limitation that only metal cations and oxygen be present in the primary component of the oxide coating. A finding of equivalence would vitiate the limitation of 'oxide coating'. . . . " *Id.* (citing *Tronzo*). On this basis, the Federal Circuit refused to remand the case for a determination of infringement under the doctrine of equivalents "because we conclude that no reasonable fact-finder could find such infringement." *Id.*. The Federal Circuit did not ask whether this difference between the accused product and the claim was "substantial."

In *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314 (Fed. Cir. 2001) the claim in question called for "a hollow tubular bat frame having a circular cross-section; and an insert positioned within the frame." *Id.* at 1319. In the accused device the positions of the insert and frame were reversed: the insert was external to, not within, the frame. The Federal Circuit affirmed the trial court's summary judgment of non-infringement under the doctrine of equivalents because "the functional relationships of these structural limitations is not maintained." *Id.* at 1333. Acknowledging that the accused device simply reversed the position of the insert and the frame, the Federal Circuit did not then ask whether that difference in arrangement was "substantial." Rather, the Federal Circuit stated that "[i]t is one thing to effect a mere reciprocal change, but it is quite another thing when a limitation in a claim is simply missing." *Id.* at 1334.

Other examples of cases in which the Federal Circuit took a "hard" approach to claim interpretation include *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed Cir. 2000) (A device's extension of only 47.8% of a length could not be equivalent to a claim element that called for the device to extend "the majority of the length," because

holding a minority to be equivalent to a majority would vitiate the majority requirement), and *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1345 (Fed Cir. 2001) (A side-by-side arrangement of tubes could not infringe a claim that specified a coaxial arrangement of tubes because "[a] particular structure can be deemed outside the reach of the doctrine of equivalents because that structure is clearly excluded from the claims whether the exclusion is express or implied."). *Id.* at 1345.

C. In Other Cases The Federal Circuit Has Taken The "Soft," Non-Literal Approach to the All-Elements Rule That It Took In *DePuy Spine*

DePuy Spine is one decision in which the Federal Circuit elected to ignore the specific wording of a claim. The Federal Circuit's thinking when it is in this "soft" mode, allowing broadening of a clearly specified claim element, is illustrated by a number of other recent cases. In *Abbott Laboratories v. Dey, L.P.*, 287 F.3d 1097 (Fed. Cir. 2002), Abbott's patent claimed a surface active material comprising a phospholipid and other ingredients, "characterized in that the overall phospholipid content is 68.6-90.7%. . . ."*Id.* at 1099. The accused product contained phospholipid up to 94.5% concentration, and Abbott presented expert testimony that the phospholipid content of the accused product was insubstantially different from the claimed phospholipid content because "95 percent [phospholipid] would work exactly the same" as the claimed 90.7%, and that "it really doesn't matter whether it is 80 or 85 or 90 or 95 or probably even 99." *Id.* at 1101. On the other hand, the expert testified that there was an upper limit to the effective content of phospholipid, probably somewhere between 99% and 100%. *Id.* Although the trial court felt that this testimony tended to establish equivalence, it ruled that Abbott was "effectively and improperly reading out the phospholipid range limitation

altogether." *Id.* at 1102. The Federal Circuit reversed, seizing upon the fact that there was *some* upper limit—although not the 90.7% stated in the claim—to allow Abbott to invoke the doctrine of equivalents. *Id.* at 1107.[3]

The Federal Circuit similarly took the "soft" approach in *Insituform Technologies, Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098 (Fed. Cir. 1996) The Federal Circuit interpreted a patent claim "as limited to 'a process using only one vacuum cup.'" *Id.* at 1106 (Internal citation omitted). Nevertheless, the Federal Circuit found that a process that used multiple cups infringed the claim under the doctrine of equivalents. *Insituform Technologies, Inc. v. Cat Contracting, Inc.*, 161 F.3d 688, 693 (Fed. Cir. 1998). In finding infringement, the Federal Circuit found no substantial differences between the claimed single-cup process and the accused multi-cup process because "the multiple cups used in the accused process each perform precisely the same steps and functions as the single cup of the claimed method. Every limitation in claim 1, therefore, is met by at least one cup in Defendants' multiple cup process." *Id.*

The "soft" approach, which eschews a literal reading of patent claims, may be fairer to some patentees in some circumstances than the unforgiving "hard" test. Yet, this approach inevitably leads to uncertainty on the part of a patentee's competitors, who will not know how "soft" any given court might be. Thus, a clear rule for allowing equivalents beyond the literal interpretation of the claims, in appropriate circumstances, must be established.

[3] "Because Abbott's application of the doctrine of equivalents to a phospholipid upper limit of 94.5% does not eliminate the upper limit of phospholipid from the claim. Abbott should not be precluded on this basis from relying on the doctrine of equivalents in this case." *Abbott Laboratories*, 287 F.3d at 1107.

D. The "Hard" Approach Does Not Satisfy This Court's Requirement for Equity for Patentees

This Court has resoundingly expressed its desire to assure that patentees are equitably treated and given the protection they deserve. This Court has, as a result, consistently expressed its faith in the doctrine of equivalents, stating that claims must not be read so literally as to "leave room for - indeed encourage - the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law." *Graver Tank,* 339 U.S. at 607. An unqualified "hard" approach to claim interpretation, as practiced by the Federal Circuit in the cases described in § I.B. *supra*, is unsatisfactory because it has the potential to "convert the protection of the patent grant into a hollow and useless thing," *id.*, resulting in inequitable treatment of patentees.

E. The "Soft" Approach Does Not Satisfy This Court's Requirement for Public Notice

This Court has also expressed its alarm at the effect of the doctrine of equivalents on the public notice function of patent claims. Indeed, the "soft" approach is nothing more than a broad application of the doctrine of equivalents, and "[t]here can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement." *Warner-Jenkinson*, 520 U.S. at 29. An unqualified "soft" approach to claim interpretation, as practiced by the Federal Circuit in the cases described in § I.C. *supra*, is therefore as unsatisfactory as an unqualified "hard" approach.

II. This Court Must Reject the Federal Circuit's Inconsistent Application of the All-Elements Rule And Endorse A Framework For Clear Application of That Rule, Such As A Determination Of Whether the Equivalent Feature in Question Was Foreseeable at the Time of Patenting

A. The All-Elements Rule Can Be An Efficient Threshold Rule When Evaluating Equivalence

DePuy Spine and *Tronzo* are examples of cases in which, had a clear method been consistently applied by the appeals court, the all-elements rule could have been (and was, in *Tronzo*) used to dispose of a theory of equivalence. In these cases the disputed claims were written with simple and unambiguously stated structural limitations. In *Tronzo*, the claim called for a conical shape, and the Federal Circuit found that there could be no equivalence because the accused product had a hemispherical shape. In *DePuy Spine*, the claim called for a spherical shape and the Federal Circuit should have ruled there could be no equivalence because the accused product had a conical shape, in analogy to *Tronzo*. In *DePuy Spine* the patentee could have attempted to obtain a patent in which the invention described in the specification and recited in the claims either specifically encompassed other shapes, or was not limited to a specific shape. The PTO would then have decided whether inventions comprising other shapes, or reciting no particular shape, were patentable.[4]

[4] The PTO granted the patentee in *Tronzo* a claim comprising a generic shape. However, the Federal Circuit declared that claim invalid as anticipated by the prior art. *Tronzo*, 156 F.3d at 1160.

B. To Preserve the Public Notice Function of Claims, Adherence To The All-Elements Rule Is Essential

Straightforward application of the all-elements rule to the literal wording of the claim in *DePuy Spine* would have definitively solved the question of infringement by equivalents, just as it did in *Tronzo*. The public expects patent claims to define the boundaries of the invention, and in these cases, which involved no nuance or subtlety of language, the public should have been able to rely on the boundaries the patentees themselves chose. But even if a court declined to apply the all-elements rule in *DePuy Spine*, it could have asked whether there was a reason that the '678 patentees could not, and should not, have claimed their invention more broadly. In the absence of such a reason, the patentee should not have access to the doctrine of equivalents to effectively re-write its claims.

C. To Preserve The Patentee's Rights, The All-Elements Rule Should Be Tempered By A Foreseeability Test

Although there are cases, such as *DePuy Spine* and *Tronzo*, in which application of the all-elements rule may be straightforward, more complex cases are not uncommon. In such cases pure literalism will not preserve all of the rights a patentee should have in his invention, as this Court has pointed out in *Graver Tank* and *Warner-Jenkinson*. To preserve those rights, pure literalism should be tempered by a rule which, in return for protection of patentee rights, is both simple to apply and properly assesses burdens between the patentee and his competitors. The foreseeability test already endorsed by this Court in *Festo* would accomplish these goals.

1. This Court's *Festo* Foreseeability Test Should Be Extended To *All* Determinations Under The Doctrine of Equivalents

This Court has already invoked a foreseeability test to regulate the application of the doctrine of equivalents in the context of prosecution history estoppel. In *Festo*, this Court set the price that a patentee must pay for having surrendered subject matter for purposes of patentability during prosecution. This price was the surrender of all equivalents to which the amendment was relevant, except for "equivalents *unforeseeable* at the time of the amendment *and* beyond a fair interpretation of what was surrendered." *Festo*, 535 U.S. at 738. (emphasis added)[5] Thus, having voiced its disinclination for pure literalism, or the "hard" approach in applying the doctrine of equivalents, this Court adopted a moderated, softened literalism, providing for a "flexible" application of the doctrine. *See id.*

However, there is no reason to limit the approach of *Festo* to the issue of prosecution history estoppel. The rationale for this Court's imposition of a foreseeability requirement to constrain the doctrine of equivalents in *Festo* applies as well when prosecution history estoppel is not implicated. Even if a patentee gave up some equivalent, or range of equivalents, by amendment, other equivalents may be conceivable—and may not have been foreseeable by the patentee. The *particular* equivalent in question might well

[5] The *Festo* decision, in detail, holds it a rebuttable presumption that prosecution history estoppel bars a finding of equivalence. A patentee can overcome the presumption if he can show the equivalent was unforeseeable, the rationale underlying his surrender was only tangentially related to the equivalent in question; or there was some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. *Festo*, 535 U.S. at 740-741.

lie in this universe of equivalents. Because the terrain of possible equivalents may outstrip the terrain surrendered by amendment, and because "[t]he patentee, as the author of the claim language, may be expected to draft claims encompassing readily known equivalents," *id.* at 740, the presumption that a patentee foresaw, or should have foreseen, a particular embodiment of his invention and did not claim it—thus surrendering it—should apply in all cases. The patentee who has not amended his claim should be held to the same standards of claim-writing as the patentee who has, and any patentee who seeks to invoke the doctrine of equivalents should be subject to the foreseeability test of *Festo*.

2. A Foreseeability Test And the All-Elements Rule Can Work Cooperatively To Properly Constrain the Doctrine of Equivalents

The method for achieving reasonable limits on the doctrine of equivalents by applying the all-elements rule in association with a foreseeability test would be straightforward. In analyzing any case of possible infringement by equivalence, the all-elements rule and foreseeability test may be applied in order. First, an accused equivalent would be examined to determine whether it satisfies the "all-elements rule." Such an examination might be relatively simple, as, for example, in cases such as *Tronzo*, where the element in question was a well-understood structural shape. If the accused equivalent could not be dismissed using the all-elements rule, the next level of analysis would be an examination in light of the foreseeability rule, in which the accused equivalent would be examined to determine whether it was, or could have been, foreseeable to the patentee. This question of fact might be answered on the basis of intrinsic evidence, including the

patent specification, and, possibly, extrinsic evidence, in the form of what was known in the prior art. If the accused equivalent was foreseeable but not claimed, then the patentee should not be permitted access to the doctrine of equivalents to effectively re-write the claim. If the accused equivalent was not foreseeable, a function/way/result or "insubstantial differences" test could be applied.

3. A Foreseeability Test Balances Public Rights And A Patentee's Rights and Responsibilities

A foreseeability test balances the public's right to know the boundaries of a patentee's claim with the patentee's right for protection against the "imitation of a patented invention which does not copy every literal detail," a right emphasized in *Graver Tank*. 339 U.S. at 608. This balance results because the test, in conjunction with the all-elements rule, reduces the subjectivity of the ultimate decision by providing a defined method for analyzing equivalence. The importance of the literal wording of a patent claim is enhanced, improving public notice, while the possibilities for going beyond this wording are clearly spelled out, both improving public notice of the possibility of equivalents and protecting the patentee from possibly excessive constraint by the literal wording of a claim.

4. A Foreseeability Test Properly Allocates Costs For Improving Patent Quality

The quality of issued patents[6] will improve if a foreseeability test is adopted. Making the costs of considering foreseeable equivalents the responsibility of the patentee puts the burden of clear claim drafting on the person holding the pen, a fair result that will require patentees to ask whether each specifically recited claim element is necessary to practice their invention.

III. This Is An Appropriate Time for This Court To Consider This Issue

A. Consideration of This Issue Now would assure consistency in This Court's Current Examination of Federal Circuit Jurisprudence

This Court is currently engaged in a critical examination of the Federal Circuit's interpretation of the patent laws since its inception a quarter-century ago. This Court has already examined Federal Circuit jurisprudence on the subjects of preliminary injunctions, *eBay v. MercExchange,* 126 S.Ct. 1837 (2006), and licensee estoppel, *MedImmune, Inc. v. Centocor, Inc.*, 127 S. Ct. 1118 (2007), and has heard argument on the Federal Circuit's criterion for determining whether an invention is "obvious," *KSR v. Teleflex*, 04-1350. (Oral argument heard on November 28, 2006). The court also recently heard argument on patent

[6] "Patent quality" has been defined in terms of how well a patent's validity can be defended in re-examination or litigation. *See Generally,* National Research Council, *A Patent System for the 21st Century* (2004), Ch. 3 (available at http://books.nap.edu/catalog.php?record_id=10976). However, the quality of a patent may also be measured by its clarity. A general measure of this quality would be the amount of infringement litigation based on the doctrine of equivalents arising in patent suits.

protection in the U.S. for software copied abroad, under 35 U.S.C. § 271(f). *A.T. & T Corp. v. Microsoft*, 05-1056. (Oral argument heard on February 21, 2007). Because the determination of infringement by equivalence is of equally critical importance to patentees and the public, clarification of this issue is necessary now, and will have significant ramifications not only in the area of patent litigation, but also in industrial development.

B. Consideration of This Issue Is Timely Specifically For This Case

This case has not had a final judgment, having been remanded to the district court for a determination of equivalence. Therefore, this case is in the same posture as *KSR International v. Teleflex, Inc.*, 04-1350, which was argued before this Court on November 28, 2006. In *KSR*, as in *DePuy Spine*, a summary judgment was vacated by the Federal Circuit, which remanded the case to the lower court.

This Court has "no absolute bar to review of non-final judgments of the lower federal courts." *Mazurek v. Armstrong*, 520 U.S. 968, 975 (1997). A ruling by this Court now would also be permissible because it would be "fundamental to the further conduct of the case"—indeed, could be dispositive. *See Gillespie v. United States Steel Corp.*, 379 U.S. 148, 152-154 (1964); *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 685, n. 3 (1949); *Land v. Dollar*, 330 U.S. 731, 734, n. 2 (1947); *United States v. General Motors Corp.*, 323 U.S. 373, 377 (1945). For these reasons, consideration of this case now by this Court is appropriate.

CONCLUSION

For the reasons stated, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

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APPENDIX A

United States Court of Appeals for the Federal Circuit
05-1311, -1335

DEPUY SPINE, INC. (formerly known as Depuy Acromed, Inc.) and BIEDERMANN MOTECH GMBH,
Plaintiffs-Appellants,

V.

MEDTRONIC SOFAMOR DANEK, INC. (formerly known as Sofamor Danek Group, Inc.) and MEDTRONIC SOFAMOR DANEK USA, INC.,
Defendants-Cross Appellants.

Kenneth R. Adamo, Jones Day, of Dallas, Texas, argued for plaintiffs-appellants. With him on the brief were Calvin P. Griffith, Robert C. Kahrl, and Patrick J. Norton, of Cleveland, Ohio; Gregory A. Castanias, of Washington, DC; and Brian J. Murray, of Chicago, Illinois.

Dirk D. Thomas, Robins Kaplan Miller & Ciresi L.L.P., of Washington, DC, argued for defendants-cross appellants. With him on the brief were Robert A. Auchter and Andre J. Bahou; and David E. Marder, of Boston, Massachusetts.

Appealed from: United States District Court for the District of Massachusetts

Senior Judge Edward F. Harrington

United States Court of Appeals for the Federal Circuit
05-1311, -1335

DEPUY SPINE, INC. (formerly known as Depuy Acromed, Inc.) and BIEDERMANN MOTECH GMBH,
Plaintiffs-Appellants,

V.

MEDTRONIC SOFAMOR DANEK, INC. (formerly known as Sofamor Danek Group, Inc.) and MEDTRONIC SOFAMOR DANEK USA, INC.,
Defendants-Cross Appellants.

DECIDED: November 20, 2006

Before NEWMAN, LINN, and PROST, *Circuit Judges*.
LINN, *Circuit Judge*.

DePuy Spine, Inc. (formerly DePuy AcroMed, Inc.) and Biedermann Motech GmbH (collectively "DePuy") appeal from grants of summary judgment that the Vertex® and bottom-loaded types of devices marketed by Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively "Medtronic") do not infringe US. Patent No. 5,207,678 ('678 patent). *DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc.* No. 01-10165-EFH (D. Mass. Apr. 14, 2003) ("*All Models Order*"); *DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-10165-EFH (D. Mass. Feb. 24, 2004) ("*Vertex Order*"). Medtronic cross-appeals from the denial of its motion for judgment as a matter of law (JMOL) and the final judgment entered after a jury verdict finding that Medtronic's MAS polyaxial pedicle screws infringe the '678 patent by equivalents and awarding lost profit damages. *DePuy Acromed, Inc. v. Medtronic*

Sofamor Danek, Inc., No. 01-10165-EFH (D. Mass. Feb. 10, 2005). We conclude that the district court erred in granting summary judgment of non-infringement on the Vertex® model. We also conclude that district court's judgment of non-infringement for the bottom-loaded screw devices was proper and that it correctly determined that Medtronic was not entitled to judgment as a matter of law on the issues of non-infringement or lost profit damages for the MAS polyaxial pedicle screws and correctly entered judgment of infringement as to the MAS device. Thus, we affirm-in-part, reverse-in-part, and remand.

BACKGROUND

DePuy Spine and Biedermann Motech are the exclusive licensee and assignee, respectively, of the '678 patent. The '678 patent involves pedicle screws and receiver members used in spinal surgeries. Pedicle screws are implanted into the vertebrae during surgery. The head of each pedicle screw is connected to a receiver portion, and a threaded rod connects the receiver portions of several screws. Together, the screws, receiver portions, and rods are used to stabilize spinal column segments.

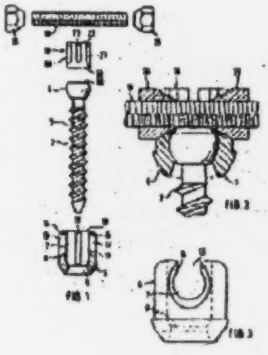
In the prior art, it was difficult for surgeons to rigidly install the screws into adjacent vertebrae in the exact positions needed to properly align the receiver portions to receive the threaded rod. To overcome this problem, improved structures were developed that used a spherical screw head and a halved receiver portion with a spherical cavity. This allowed pivoted movement of the receiver portion much like a ball-and-socket joint, but required precise machining of matching spherical portions of different sizes and therefore resulted in high stocking costs.

The '678 patent attempts to reduce stocking costs for pedicle screws by using a uniform receiver portion that can be placed

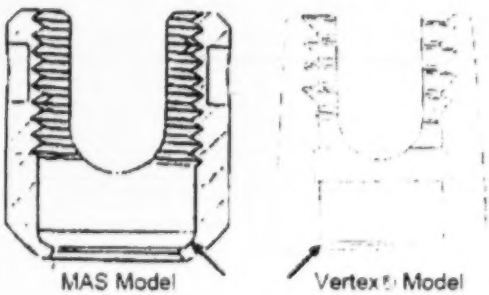
on different sizes of spherical heads. Claim 1 is representative of all claims on appeal:

> 1.Device for stabilizing spinal column segments, comprising a pedicle screw (1) having a threaded shaft portion (3) and a spherically-shaped head (4) at the end of said threaded shaft portion, a receiver member (5) flexibly connected to said head (4), said receiver member being provided with two holes for receiving a rod 916) [sic:(16)], a receiver chamber (7) being provided within said receiver member (5), the receiver chamber (7) having at one end thereof *a bore (8) for passing the threaded shaft portion 13) therethrough* and *an inner hollow spherically-shaped portion* (9) for receiving the head (4) of said screw (1), *an opening (10) being provided opposite said bore (8) for inserting said screw* (1), said device further comprising *a compression member* (18) for exerting a force onto said head (4) such that said head is *pressed against the hollow spherically-shaped portion* (9).

'678 patent, col. 4, II. 9-24 (emphasis added). The highlighted limitations are at issue on appeal and are termed, respectively, as the "bore," "spherically-shaped,'' "opening," "compression member, " and "pressed against" limitations. The invention is illustrated in figures 1 through 3 of the '678 patent, which are reproduced below:



On January 26, 2001, DePuy filed suit against Medtronic asserting infringement of the '678 patent based on Medtronic's MAS, Vertex®, M8, M10, and Sextant models of polyaxial pedicle screws. The MAS and Vertex® models are assembled by placing the screw through a top opening in the receiver member and then securing the top with a crown. In the Vertex® model, the interior portion of the receiver member adjacent to the screw head is of an approximately conical shape; the same area in the MAS model is shaped like a portion of a toroid. The receiver portions for the MAS and Vertex® models are depicted below, with arrows indicating the relevant conical and toroidal portions.



The M8, M10, and Sextant models ("the bottom-loaded screw models") are assembled by first inserting the crown and screw head into the bottom of the receiver member and then inserting a "snap ring." The snap ring in the bottom-loaded screw models retains the screw head in a manner similar to how the conical or toroidal areas in the MAS and Vertex® models retain the screw head. In the bottom-loaded screw models, the screw head is too large to pass through the opening at the top of the receiver member.

Medtronic filed three motions seeking summary judgment of non-infringement in January 2003. The first motion asserted that all models lacked the "compression member" limitation, and the second motion asserted that the Vertex® and MAS

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models lacked the "spherically-shaped" limitation. Both motions were denied. *All Models Order*, slip op. at 1. The third motion asserted that the bottom-loaded screw models did not possess either the "bore" or "opening" limitations. The district court granted the third motion, concluding that the bottom-loaded screw models lacked the "bore" limitation literally and that the doctrine of equivalents could not be applied without vitiating that limitation. *Id.*, slip op. at 2-3.

The court then conducted a hearing on claim construction and construed two terms at issue in this appeal. The court's construction of those terms is contained in a Memorandum Opinion and Order dated October 27, 2003. *DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-10165-EFH (D. Mass. Oct. 27, 2003) ("*Claim Construction Order*"). The court construed the "spherically-shaped" limitation to mean "approximately spherical, such as a globe or basketball." *Id.*, slip op. at 17. The court also construed the "compression member" limitation and held that it was not a means- plus-function claim limitation; instead, it construed that limitation "to require an intermediate piece (or member) that applies compression force to the head of the screw." *Id.*

Based on the court's construction of the "spherically-shaped" limitation, Medtronic filed a motion for summary judgment of non-infringement for the Vertex® model. *Vertex Order*, slip op. at 1. The court concluded that the Vertex® model did not literally infringe the '678 patent because the inner hollow space of the receiver member had a conical shape that was not approximately spherical. *Id.*, slip op. at 2. The court also concluded that the Vertex® model did not infringe under the doctrine of equivalents. *Id.*, slip op. at 3. Citing *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998), the court held that under the "all elements" rule, it could not find a conical shape to be equivalent to a spherical shape without reading the limitation out of the claim. *Id.*, slip op. at 4. The court also found that the Vertex® model did not do "substantially the

same thing" as the device in the '678 patent because the screw head contacts an edge of the receiver member rather than a larger area. *Id.*, slip op. at 5.

The case proceeded to a jury trial on the MAS model. The jury verdict found that the MAS model infringed the '678 patent under the doctrine of equivalents and awarded lost profits and reasonable royalty damages. Medtronic moved for judgment as a matter of law that the MAS model did not infringe under the doctrine of equivalents and that DePuy was not entitled to lost profit damages; both motions were denied.

On appeal, DePuy challenges the court's finding that no issue of material fact exists as to whether the bottom-loaded screw and Vertex® models infringe the '678 patent and the court's application of the "all elements" rule. On cross-appeal, Medtronic challenges the courts construction of the "compression member" limitation and the court's denial of its motions for JMOL. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

This court reviews a district court's grant of summary judgment of non-infringement *de novo*. *Hilgraeve Corp. v. McAfee Assocs., Inc.*, 224 F.3d 1349, 1352 (Fed. Cir. 2000). Summary judgment is proper only if there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

Claim construction is an issue of law, *see Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996), that we review *de novo*. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1328

(Fed. Cir. 2005) (*en banc*); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (*en banc*). Infringement, whether literal or under the doctrine of equivalents, is a question of fact. *Ferguson Beauregard v. Mega Sys., Inc.*, 350 F.3d 1327, 1338 (Fed. Cir. 2003). The determination of infringement under the doctrine of equivalents is limited by two primary legal doctrines, prosecution history estoppel and the "all elements" rule, the applications of which are questions of law. *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1378 (Fed. Cir. 2005).

"We review the district court's denial of a motion for JMOL without deference, applying the same standard employed by the district court." *Honeywell, Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004) (*en banc*). Federal Rule of Civil Procedure 50(a)(1) provides that a court may grant a motion for JMOL only where "there is no legally sufficient evidentiary basis for a reasonable jury to find for [the non-movant]." Fed. R. Civ. P. 50(a)(1).

"Whether lost profits are legally compensable in a particular situation is a question of law that we review *de novo*." *Poly-America, L.P. v. GSE Lighting Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004).

Interpretation of contract terms is a matter not unique to our exclusive jurisdiction and is therefore reviewed under regional circuit law. *See Sun Studs, Inc. v. Applied Theory Assocs., Inc.*, 772 F.2d 1557, 1561 (Fed. Cir. 1985). The First Circuit treats interpretation of contract terms as a legal question reviewed *de novo*, unless there is such ambiguity in the language as to create a question of fact. *Liberty Mut. Ins. Co. v. Greenwich Ins. Co.*, 417 F.3d 193, 196-97 (1st Cir. 2005). Whether ambiguity exists is considered a question of law. *Id.*

II. Vertex® Model

DePuy argues that the district court improperly granted summary judgment of non-infringement on the Vertex® model because a genuine issue of material fact exists on both literal infringement and infringement under the doctrine of equivalents. With respect to the doctrine of equivalents, DePuy argues that the court erred in applying both the "all elements" rule and the function-way-result test.

Medtronic counters that the receiver member of the Vertex® device has a conically-shaped hollow portion, rather than a spherically-shaped portion, and therefore does not literally infringe. Medtronic also counters that the court properly applied the relevant law in examining infringement by equivalents. Alternatively, Medtronic counters that even if a "spherically-shaped" equivalent is present in the Vertex® model, the Vertex® model does not meet the "pressed against" limitation because the screw head rests against an edge of the equivalent and not against the actual spherically-shaped portion equivalent. We will begin our analysis with Medtronic's alternative argument.

A. "Spherically-Shaped" and "Pressed Against"

Claim 1 recites that the screw "head is pressed against the hollow spherically- shaped portion." The court construed "spherically-shaped" to mean "approximately spherical, such as a globe or a basketball." The parties do not dispute this construction on appeal. The parties dispute, however, whether the "pressed against" limitation requires that the screw head engage the entire spherically-shaped portion or whether it is enough that the head engage just the "edge" of the spherically-shaped portion.

In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record,

examining the claim language itself, the written description, and the prosecution history, if in evidence. *See Phillips*, 415 F.3d at 1312- 17. First, the claim language does not indicate that "hollow spherically-shaped portion" must be limited so as not to include the edge of that portion, nor does it indicate how much of the hollow spherically-shaped portion must be "pressed against" the screw head. Claim 4, which depends from claim 1, requires that "the radii of the hollow spherically-shaped portions (9, 19) and of the spherically-shaped screw head (4) [be] substantially equal." '678 patent, col. 4, II. 37-40. That implies that independent claim 4 must be broad enough to read on a device with components of unequal radii that nonetheless are pressed against each other. If the screw head has a smaller radius than the hollow spherically-shaped portion, the only part of the spherically-shaped portion against which the screw head would be pressed would be the edge of the hollow spherically-shaped portion.

Second, the specification does not indicate that the "hollow spherically-shaped portion" must be limited to exclude the edge of that portion or that "pressed against" requires a certain amount of contact between the spherically-shaped portion and the screw head. In the absence of a stated reason to exclude the edge, it would ordinarily and customarily be understood that the referenced portion includes any and all parts of the structure. Similarly, in the absence of a stated reason to require a certain amount of contact, it would ordinarily and customarily be understood that the referenced portion is pressed against a screw head when any amount of that portion presses against the screw head. Figures 1 and 2 of the '678 patent depict hollow spherically-shaped portion 9 in crosshatching that appears to include the edge of the portion. The corresponding description of that portion does not exclude the edge, noting that "[a] portion 9 in the form of a hollow spherical segment is provided in the interior immediately adjacent to the bore." '678 patent, col. 2, II. 21-

23. That description indicates that the relevant portion extends all the way to the bore, which necessarily implies that it includes the edge. Further, the description does not indicate how much of the spherically-shaped portion presses against the screw head; rather, it notes only that there is "contact" between the components. *Id.*, col. 2, 11. 33-34. The prosecution history provides no further guidance.

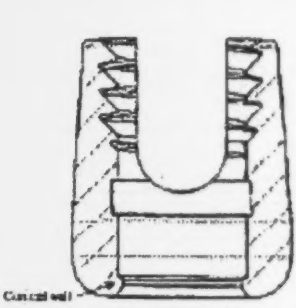
For the foregoing reasons, we find Medtronic's argument unpersuasive, and we conclude that "hollow spherically-shaped portion" includes the edge of that portion and that the screw head is "pressed against" the "hollow spherically-shaped portion" if it presses against all or any part of that portion-including the edge.

B. Conical Walls

The district court found that there was not a genuine issue of material fact as to literal infringement because the shape of the inner hollow space in the Vertex® model is conical, with "angular rather than spherical" walls. *Vertex Order*, slip op. at 2-3. The court also found that even if a portion of the shape is spherical, that spherically-shaped portion does not contact the head of the screw. *Id.*, slip op. at 3.

On appeal, DePuy points to two comparisons as evincing a question of fact regarding a spherically-shaped portion in the Vertex® model. First, DePuy points to pictures of a basketball and a selected portion of the basketball, which DePuy submitted as exhibits before the district court. DePuy argues that the picture of the selected portion demonstrates that a thin slice of a sphere creates a profile that appears conical. Depictions of those exhibits are shown below:

Second, DePuy points to a comparison of a cross section of the Vertex® model and Figure 3 of the '678 patent. That comparison is shown in the following figures, arrows added to indicate the relevant conical and spherical walls:



Vertex® Model

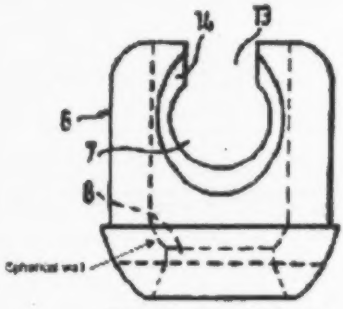


Figure 3 of the '675 Patent

DePuy argues that, like the selected portion of the basketball, the Vertex® model could be viewed as possessing a spherically-shaped portion that appears conical in profile.

Although these comparisons do highlight that at varying degrees of magnification or abstraction a curved surface can appear angular, they do not create a genuine issue of material fact as to whether the Vertex® model possesses the "spherically-shaped" limitation. DePuy points to no evidence that specifically identifies a region in the Vertex® model as "spherical." Indeed, DePuy's expert acknowledged that the engineering drawing of the Vertex® model shows a "conically-shaped" hollow portion, and that a photomicrograph of the Vertex® receiver shows a ledge--not

a sphere--even if it contains some rounding at the edges. At best, these declarations identify a conical or ledge structure; they do not constitute evidence of a portion that meets the literal terms "approximately spherical, such as a globe or a basketball." Therefore, the district court did not err in concluding that there was no genuine issue of material fact as to literal infringement.

C. Doctrine of Equivalents

The district court determined that it "cannot find that the cylindrical-conical shape of [the Vertex® model's] receiver member is equivalent to the spherically-shaped portion disclosed in the '678 patent." *Vertex Order*, slip op. at 4. The court first applied the "all elements" rule and concluded that, as in *Tronzo*, treating a conical shape as the equivalent of a spherical shape would vitiate the "spherically-shaped" limitation. *Id.* The court also applied the function-way-result test and determined that, because the screw head in the Vertex® model "is merely pressed against an edge or lip on the receiver member," the Vertex® model does not do "substantially the same thing" as the device in the '678 patent. *Id.*, slip op. at 5.

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)). The doctrine recognizes that

> [t]he language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty. If patents were always interpreted by their literal terms, their

> value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002); *Graver Tank*, 339 U.S. at 605 ("[T]o permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing.").

One limit on the doctrine of equivalents is the "all elements" rule. The "all elements" rule attempts to balance the doctrine of equivalents with the basic patent law principle that claim language defines the scope of an invention and every limitation is material.

> Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.

Warner-Jenkinson, 520 U.S. at 29. Thus, as a practical matter, the "all elements" rule informs a doctrine of equivalents analysis by requiring that equivalence be assessed on a limitation-by-limitation basis, rather than from the perspective of the invention as a whole, and that no limitation be read completely out of the claim. *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005).

In *Warner-Jenkinson*, the Supreme Court provided guidance for determining when resort to the doctrine of equivalents is

precluded as a matter of law. First, the Court noted that "[w]here the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment." *Warner-Jenkinson*, 520 U.S. at 39 n.8 (citing Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 US. 317, 322-23 (1986)). Second, the Court noted that "under the particular facts of a case, . . . if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court." *Id.* at 39 n.8.

Informed by this guidance, we have held that in certain instances, the "all elements" rule forecloses resort to the doctrine of equivalents because, on the facts or theories presented in a case, a limitation would be read completely out of the claim – i.e., the limitation would be effectively removed or "vitiated." For instance, we have concluded that in some cases, the evidence was such that no reasonable jury could determine a proffered equivalent to be insubstantially different from the claimed limitation. *See, e.g., Freedman Seating*, 420 F.3d at 1361 (holding that a limitation was vitiated in part because the structural difference in the accused device "is not a 'subtle difference in degree,' but rather 'a clear, substantial difference or difference in kind'" (internal citation omitted)); *Ethicon*, 149 F.3d 1309, 1319 (Fed. Cir. 1998) (holding that the "all elements" rule barred application of the doctrine of equivalents because, on the facts presented, no reasonable jury could find the differences to be insubstantial). We have also concluded that in some cases, the patentee's theory of equivalence was legally insufficient because, rather than demonstrate an insubstantial difference between a limitation and an element in the accused device, the theory effectively eliminated a limitation in its entirety. *See, e.g., Tronzo*, 156 F.3d at 1160 (holding that the patentee's theory of equivalence – that "any shape would be equivalent to the conical limitation" – would write such a limitation out of the claims (emphasis in original)); *Forest*

Labs., Inc. v. Abbot Labs., 239 F.3d 1305, 1313 (Fed. Cir. 2001) (holding that the patentee's theory of equivalence--that a limitation on the percentages of water in a composition was "irrelevant" when compared to the accused composition--vitiated such a limitation). Thus, the "all elements" rule generally is not met--and therefore a claim limitation can be said to be vitiated--if the theory or evidence of equivalence is legally incapable of establishing that the differences between the limitation in the claim and the accused device are insubstantial; i.e., if the theory or evidence is so legally insufficient as to warrant a holding of non-infringement as a matter of law. *Warner-Jenkinson*, 520 U.S. at 39 n.8; *Metro. R.R. Co. v. Moore*, 121 U.S. 558, 569 (1887) ("Strictly speaking, evidence is said to be insufficient in law only in those cases where there is a total absence of such proof, either as to its quantity or kind, as in the particular case some rule of law requires as essential to the establishment of the fact."); *see also Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425-26, 1429-30 (Fed. Cir. 1997).

Our decision in *Sage Products*, decided shortly after *Warner-Jenkinson*, illustrates the genesis of such an analysis. For one invention in that case, we held that resort to the doctrine of equivalents was foreclosed because no reasonable jury could find that the differences in the accused device were insubstantial. *Sage Products*, 126 F.3d at 1423-26. In considering equivalence, we noted the simplicity of the structure, the specificity and narrowness of the claim, and the foreseeability of variations at the time the claim was filed. *Id.* at 1425 ("No subtlety of language or complexity of the technology, nor any subsequent change in the state of the art, such as later-developed technology, obfuscated the significance of this limitation at the time of its incorporation."). Because under these particular facts, no reasonable jury could find that the differences in the accused device were insubstantial, we concluded that a finding of infringement by equivalents would effectively remove the

relevant limitations from the claim and affirmed the district court's summary judgment of non-infringement. *Id.* at 1425-26.

For a second invention at issue in *Sage Products*, we held that the doctrine of equivalents was foreclosed because the patentee's theory of infringement was improper. *Id.* at 1429-30. In considering equivalence for a means-plus-function limitation, we noted that the claimed function included the ability to control access by moving between open and closed positions. *Id.* at 1428-29. The accused product used a permanently locking lid that could not move back to an open position. *Id.* at 1427. We noted that the patentee's theory of equivalence – that a permanently locking lid is equivalent to an openable lid – was unsustainable in that it did not offer a "function equivalent to that expressly recited in the claimed element." *Id.* at 1429. Because that theory could not support a conclusion of equivalence regardless of the evidence, we concluded that the theory was legally insufficient, declined to apply the doctrine of equivalents, and affirmed the court's summary judgment of non-infringement. *Id.* at 1429-30.

It is important to note that when we have held that the doctrine of equivalents cannot be applied to an accused device because it "vitiates" a claim limitation, it was not to hold that the doctrine is always foreclosed whenever a claim limitation does not literally read on an element of an accused device; such an interpretation of the "all elements" rule would swallow the doctrine of equivalents entirely. *See Ethicon*, 149 F.3d at 1316-17 (holding that a similar interpretation "would force the All Elements rule to swallow the doctrine of equivalents, reducing the application of the doctrine to nothing more than a repeated analysis of literal infringement" (footnote omitted)). "'[A]ny analysis of infringement under the doctrine of equivalents *necessarily* deals with subject matter that is 'beyond,' 'ignored' by, and not included in the literal scope of a claim." id. at 1317 (emphasis in original). A

holding that the doctrine of equivalents cannot be applied to an accused device because it "vitiates" a claim limitation is nothing more than a conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency.

Here, in applying the "all elements" rule, the district court relied solely on *Tronzo* and concluded that "the cylindrical-conical shape of the [Vertex® model] cannot infringe the '678 patent without *reading out* of the claim the express requirement that the screw head be 'pressed against the hollow, spherically-shaped portion.'" *Vertex Order*, slip op. at 4 (emphasis added). The court also noted that "permitting the cylindrical-conical shape of the [Vertex® model] to be considered equivalent to the spherical shape required by the '678 patent *vitiates* the '678 patent requirement that the spherically-shaped head . . . be pressed against an inner, hollow, spherically-shaped portion of the receiver member." *Id.*, slip op. at 4 n.3 (emphasis added). The district court also determined that this conclusion was supported by the function-way-result test because the conically-shaped portion of the Vertex® model and the "spherically-shaped" limitation of the claim do not "do 'substantially the same thing.'" *Id.*, slip op. at 5.

We find no support in the present case for the district court's conclusion that applying the doctrine of equivalents would vitiate or read out the "spherically-shaped" limitation. Our decision in *Tronzo* is factually distinguishable.[1] In *Tronzo*, the

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[1] As we noted in *Optical Disc Corp. v. Del Mar Avionics*, "*Tronzo* does not stand for the proposition that a claim limitation describing a specific shape of a claimed structure cannot be infringed under the doctrine of equivalents by a differently shaped structure." 208 F.3d 1324, 1337 (Fed. Cir. 2000). Instead, *Tronzo* is limited to the facts and theories of equivalence presented in that case.

invention related to artificial hip sockets and the patent at issue was a continuation-in-part. 156 F.3d at 1156-57. The independent claims that were added in the continuation covered a prosthesis socket with no specific shape. *Id.* at 1157-58. Because the written description only disclosed a conical shape for the prosthesis and characterized other shapes as "prior art" and "inferior" to a conical shape, we held that the independent claims were unsupported by the written description, not entitled to the parent's filing date, and thus invalid in view of intervening prior art. *See id.* at 1158-60. The only valid claims at issue in *Tronzo* were dependent claims that limited the prosthesis body to having "a generally conical outer surface." The patentee attempted to prove infringement of an accused product with a hemispherical outer surface under the doctrine of equivalents because, "[a]ccording to the expert testimony, *any* shape would be equivalent to the conical limitation." *Id.* at 1160 (emphasis in original). The theory of equivalence, therefore, did not identify a specific element of the accused product as an equivalent to the "generally conical" limitation; rather, the patentee argued that *any* shape would be equivalent to a conical shape, despite clear indications in the written description to the contrary. We concluded that such a theory was insufficient as a matter of law and thus "would write the 'generally conical outer surface' limitation out the claims." *Id.* (citing *Warner-Jenkinson*, 520 U.S. at 39 n.8). Accordingly, we reversed the finding of infringement under the doctrine of equivalents. *Id.*

Here, unlike the patentee in *Tronzo*, DePuy did not propose that any shape would meet the "spherically-shaped" limitation. Rather, DePuy's expert presented particularized declaration demonstrating its theory that a specific element of the accused device-the hollow conically-shaped portion of the receiver member-was insubstantially different from the corresponding "spherically-shaped" limitation because it

supported the screw head, allowed for flexible movement, and--when the compression member is engaged--creates a rigid lock between the screw head and the receiver. Indeed, the expert expressly identified certain shapes that were different from the accused device but would *not* be capable of supporting the screw head allowing flexible movement, and creating a rigid lock when the compression member is engaged. Also, unlike the patent at issue in *Tronzo*, the written description in the '678 patent does not label other shapes as "prior art" and "inferior." Thus, unlike the theory presented in *Tronzo*, DePuy's theory of equivalence was not improper.

The district court also erred in concluding that no reasonable jury could find the conically-shaped portion to be an equivalent to the "spherically-shaped" limitation because it does not do "substantially the same thing." The district court's conclusion rested solely on the fact that the screw head in the Vertex® model contacts an edge of the hollow portion as opposed to pressing against a much larger area. *Vertex Order*, slip op. at 5. As discussed above, properly construed, the "hollow spherically-shaped portion" includes the edge of that portion. Because the screw head in the Vertex® model presses against an edge of a hollow conically-shaped portion argued to be an equivalent of the "spherically-shaped" limitation, a question of fact exists as to whether the difference in the equivalent is substantial.

Because DePuy's theory of equivalence is not legally insufficient, and because we find that a question of fact exists as to whether the difference between the "spherically-shaped" limitation and the alleged equivalent is substantial, we hold that the district court erred in granting summary judgment of non-infringement under the doctrine of equivalents for the Vertex® model.

III. Bottom-Loaded Screw Models

DePuy argues that the district court erred in granting summary judgment of non- infringement for the bottom-loaded screw models because the court reached its determination without construing the "bore" limitation on which the decision was based. DePuy also argues that, to the extent a de facto construction was used in the court's analysis, the construction incorrectly added a process limitation to a product claim by construing "passing" to mean that a screw shaft must move through the bore. DePuy argues that "passing" means that the screw shaft is positioned to extend through the bore and does not imply movement. Alternatively, DePuy argues that even if "passing" does imply movement, the screw shaft moves through a snap ring element that meets the "bore" limitation literally or as an equivalent.

Medtronic counters that DePuy's argument that "passing" means "extending" was waived because it was first advanced on a motion for reconsideration and not originally argued in opposition to Medtronic's summary judgment motion. Medtronic also counters that the district court correctly construed the "bore" limitation as requiring a bore that is part of the receiver chamber when a threaded screw shaft moves through it, and that such a construction does not import a process limitation into the claims. In passing, Medtronic asserts that the district court recognized that the bottom-loaded screw models also lacked the "opening" limitation and that this limitation provides a further basis for affirming summary judgment of non-infringement.

Although the district court quoted language from claim 1 of the '678 patent that included the "opening" limitation, it is clear that the court based its conclusion on the "bore" limitation and not the "opening" limitation. *See All Models Order*, slip op. at 2 ("In particular, the defendant's [bottom-loaded screw models] lack '. . . the receiver chamber (7)

having at one end thereof a bore for passing the threaded shaft portion (3) therethrough.'"). Indeed, the entirety of the infringement analysis was focused on whether the bottom-loaded screw models possessed the "bore" limitation:

> It is important to the Court's conclusion that claim 1 requires the bore, through which the threaded shaft of the screw must pass, to be part of the receiver chamber. . . . Because Medtronic's [bottom-loaded screw models] do not embody this limitation, they do not literally infringe claim 1. Nor can infringement be found through application of the doctrine of equivalents."

Id., slip op. at 2-3 (citations omitted). Thus, nothing in the district court's summary judgment opinion addresses the "opening" limitation. However, "[w]e sit to review judgments, not opinions." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983). The issue was fully argued below and has been raised by Medrad on appeal; we therefore may address the "opening" limitation. *See Glaxo, Inc. v. Torpharm, Inc.*, 153 F.3d 1366, 1371-72 (Fed. Cir. 1998) ("When a matter comes before an appellate court following summary judgment, the appellate court is free to adopt a ground advanced by the appellee in seeking summary judgment but not adopted by the trial court.").

The language of claim 1 of the '678 patent claims a receiver member with a bore at one end and an opening "opposite said bore (8) for inserting said screw." The claim language therefore identifies two clear requirements for the opening: (1) it must be physically located opposite from the bore and (2) it must be "for inserting said screw." The specification indicates that the opening 10 and hollow cylindrical portion 11 must be of sufficient size to allow the screw head 4 to be inserted into the hollow spherical- segment-shaped portion 9. '678 patent, col. 2, ll. 21-34. Thus, when read in view of the

specification, "for inserting said screw" is a functional limitation that requires that the opening be capable of inserting the screw. We therefore construe the "opening" limitation to mean that there must be an opening in the receiver member that is opposite the bore and is capable of inserting the screw.

Medtronic asserts – and DePuy does not contest – that the aperture at the top of the bottom-loaded screw models is not capable of inserting the screw because the diameter of that aperture is smaller than the diameter of the screw head. Medtronic argues that this aperture does not meet the requirements of the "opening" limitation. DePuy appears to counter that the interior space of the receiver member-and not the top aperture-meets the requirement of the "opening" limitation.

We agree with Medtronic. DePuy's theory of infringement argues that the snap ring in the bottom-loaded screw models satisfies the "bore" limitation. Once assembled, the interior space of the receiver member is located next to such bore, not opposite to it. The only aperture that is opposite to the "bore" that DePuy advances is the aperture at the top of the receiver member. However, because it is uncontested that the screw cannot be inserted through that aperture, it cannot meet the functional restriction of the "opening" limitation. Therefore, we conclude as a matter of law that the bottom-loaded screw models do not posses the "opening" limitation and affirm the district court's summary judgment on that basis. Because we affirm summary judgment of no infringement on the basis of the "opening" limitation, we need not address DePuy's arguments with respect to the "bore" limitation.

IV. MAS Model

On cross-appeal, Medtronic argues that the district court erred in denying its motion for JMOL of non-infringement of the

MAS model because DePuy failed to offer evidence that the MAS model possessed an equivalent to the "pressed against" limitation that performed substantially the same function, in substantially the same way, to achieve substantially the same result. Specifically, Medtronic acknowledges that DePuy offered function-way-result evidence related to the "hollow spherically-shaped portion" limitation, but argues that no function-way-result evidence was offered demonstrating that pressing against an edge of a hollow portion is the equivalent of pressing against a hollow portion. Medtronic also argues that the court erred in denying its motion because the jury's finding of infringement by equivalence vitiated the "spherically-shaped" limitation. Medtronic argues that here, as in *Tronzo*, DePuy's expert offered a theory that "any shape" would meet the "spherically-shaped" limitation, which reads "spherically-shaped" out of the claim.

DePuy counters that it introduced expert testimony that the MAS device possessed an equivalent to the "spherically-shaped" limitation and that the screw head literally presses against that equivalent. DePuy also counters that its expert did not testify to an "any shape will do" theory of equivalence.

Medtronic's arguments are unpersuasive. First, as discussed in Part II.A, supra, the proper construction of "hollow spherically-shaped portion" includes the edge of that portion. There is no dispute that DePuy presented sufficient evidence that the MAS models possessed the "hollow spherically-shaped portion" or its equivalent. DePuy also presented evidence that the MAS model literally meets the "pressed against" limitation when its expert testified that the screw head presses against an edge of a hollow spherically-shaped portion or the edge of an equivalent. That evidence, together with reasonable inferences in favor of the verdict, make clear that Medtronic was not entitled to judgment as a matter of law on this issue.

Second, DePuy's expert did not offer an "any shape will do" theory of equivalence similar to the theory offered in *Tronzo*. In *Tronzo*, the expert did not identify a specific element in the accused device that was an equivalent to the "generally conical" limitation, but rather testified that any shape would be an equivalent to such a limitation. 156 F.3d at 1160. Here, DePuy's expert testified that the specific hollow shape of the MAS model was equivalent to the "spherically-shaped" limitation according to the function-way-result test. The "any shape" testimony cited by Medtronic was a reference to earlier deposition testimony on cross-examination and ignores the witness's explanation on redirect. On redirect, the expert explained that at the deposition, he believed the question was directed to whether the "spherically-shaped" limitation had to be literally present in an accused device. His answer reflected his belief that an equivalent would meet the same limitation. Such an exchange at trial does not constitute an assertion or admission that "any shape" meets the "spherically- shaped" limitation. Because DePuy did not offer a legally insufficient theory of equivalence, Medtronic is not entitled to judgment as a matter of law on this issue.

V. All Accused Devices

Finally, Medtronic argues that the district court failed to properly construe the "compression member" limitation as a means-plus-function limitation, and that under a proper construction, all three accused devices do not infringe. Relying on *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1213 (Fed. Cir. 1998), Medtronic argues on cross-appeal that "compression member" is properly construed as a means-plus- function limitation despite the absence of the term "means" and that when the claims are so construed, none of the accused structures infringe. Specifically, Medtronic argues that claim 1 of the '678 patent identifies "compression member" only in terms of function, not structure, and that no

credible extrinsic evidence demonstrates that the term has a well-understood structural meaning in the relevant art.

DePuy counters that the absence of the term "means" creates a presumption that "compression member" is not a means-plus-function limitation, that all testifying engineers recognized that the term "compression member" referred to a well-known class of structures, that claim 1 itself imposes certain constraints on the structure of the compression member, and thus the district court's construction was correct.

"Means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function." *Phillips*, 415 F.3d at 1311 (citing *Watts v. XL Sys. Inc.*, 232 F.3d 877, 880-81 (Fed. Cir. 2000)). "[A] claim term that does not use 'means' will trigger the rebuttable presumption that [35 U.S.C.] § 112 ¶ 6 does not apply." *CCS Fitness v. Brunswick Corp*, 288 F.3d 1359, 1369 (Fed. Cir. 2002). This presumption can be rebutted "by showing that the claim element recite[s] a function without reciting sufficient structure for performing that function." *Watts*, 232 F.3d at 880. "Our cases make clear, however, that the presumption flowing from the absence of the term 'means' is a strong one that is not readily overcome." *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1358 (Fed. Cir. 2004).

Here, the "compression member" limitation does not use the term "means," and the presumption against means-plus-function treatment is not overcome. The claims and the specification unmistakably establish that "compression member" refers to particular structure. The claim language demonstrates that the compression member must fit inside the cylindrical opening and be of sufficient size to exert a force on the screw head, which implies structure. '678 patent, col. 4, ll. 22-24. The specification likewise makes clear that the term "compression member" refers to a particular cylindrical insert and is not simply a general reference to any structure

that will perform a particular function. *See id.*, col. 2, l. 58-col. 3, l. 16, col. 3, l. 44-col. 4, l. 6. The prosecution history, while in evidence, provides no further guidance one way or the other. However, dictionary definitions and experts on *both* sides confirm that "compression member" is an expression that was understood by persons of ordinary skill in the art to describe a kind of structure. *See Lighting World*, 382 F.3d at 1358 ("The task of determining whether the limitation in question should be regarded as a means-plus-function limitation . . . is a question on which evidence from experts may be relevant.").

Moreover, *Mas-Hamilton* is not applicable here. In that case, no other claim terms attributed structural significance to the elements at issue, and there was no evidence that the term at issue had an understood structural meaning in the art. *Mas-Hamilton*, 156 F.3d at 1213-15 ("[W]e do not see that the remaining terms in the claim limitation . . . provide any structure necessary to remove this limitation from the ambit of section 112, ¶ 6."); *id* at 1215 ("The district court determined that there was no evidence that a 'movable link member' has a well-understood structural meaning in the art."). That is not the case here. Instead, the overall impression of the claims and specification of the '678 patent is that "compression member" implied structure to one of ordinary skill in the art. This is shown by the intrinsic record and confirmed by the extrinsic evidence. Accordingly, we reject Medtronic's argument that the district court erred in not construing "compression member" as a means-plus-function limitation and in not finding non-infringement of all three models on that basis.

VI. JMOL on Lost Profit Damages

Medtronic argues on cross-appeal that the court erred in denying its motion for JMOL on the subject of lost profits because DePuy Spine did not become an exclusive licensee of

Biedermann Motech's '678 patent until the 1999 Exclusive License Agreement was entered into on August 31, 1999. Because Biedermann Motech lacked manufacturing and marketing capacity to meet demand, Medtronic argues that neither party can claim lost profit damages prior to that date and that the jury's judgment awarding damages from before that date should be adjusted.

DePuy counters that determining an exclusive licensee relationship is a factual matter and that substantial evidence supports the jury's finding that an exclusive licensee relationship was created by a 1993 Technology Agreement that became operative with respect to the '678 patent in January 1998. DePuy argues that the 1999 Exclusive License Agreement merely confirmed the rights created by the 1993 Technology Agreement. Medtronic replies that determining the date when lost profits are legally compensable is a question of law and that the district court determined when DePuy Spine became an exclusive licensee in an Order dated November 18, 2002.

Medtronic replies that a 1993 Exclusive License Agreement specifically addressed patent rights whereas the 1993 Technology Agreement did not, and that therefore the 1993 Technology Agreement could not form the basis for an exclusive license under the '678 patent.
Whether DePuy Spine is entitled to lost profits is a question of law. *Poly-America*, 383 F.3d at 1310-11. DePuy's assertion that determining whether an exclusive license exists is a factual matter is based on *Wang Laboratories v. Mitsubishi Electronics*, 103 F.3d 1571 (Fed. Cir. 1997). *Wang Laboratories* dealt with whether an implied license was created as a result of the parties' conduct. *Id.* at 1578. Though the parties in *Wang Laboratories* agreed to submit that question to the jury, *id.*, we recognized that the ultimate conclusion was a legal one that was based on underlying findings of fact regarding the parties' conduct and the

existence of consideration, *id.* at 1579-80. Here, the underlying facts are not in dispute. Accordingly, we review this issue *de novo*.

Medtronic limits its cross-appeal to a challenge of the jury's lost profit award during the period prior to the 1999 Exclusive License Agreement, arguing that (1) DePuy Spine was not an exclusive licensee during the relevant time period, and therefore its lost profits were not recoverable; and (2) Biedermann Motech lacked manufacturing and marketing capacity to meet demand, and therefore it had no basis to recover its own lost profits. Medtronic does not contest that if DePuy Spine was an exclusive licensee during the relevant time period, it is entitled to the lost profits at issue here. *See Weinar v. Rollform Inc.*, 744 F.2d 797, 806-08 (Fed. Cir. 1984) (affirming an award of lost profit damages to a licensee with the exclusive right to sell in the entire United States). We begin our analysis by determining whether DePuy Spine was an exclusive licensee of the '678 patent during the relevant time period.

Medtronic's assertion that the district court ruled on this issue with finality in its November 18, 2002 Order is incorrect. In that Order, the court stated that "[t]he standing of Plaintiff DePuy Acromed, Inc., commenced on August 31, 1999, when Biedermann Motech granted DePuy Acromed an exclusive license to the '678 patent." *DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-10165-EFH (D. Mass. Nov. 18, 2002). To the extent this order reflected the court's initial conclusion, that conclusion was apparently reversed. In denying Medtronic's motion in limine to exclude evidence of lost profits damages before August 31, 1999, the district court found that "Biedermann Motech can recover lost profits [before August 31, 1999] because it was 'closely tied' via a joint venture to the manufacturer, DePuy Acromed, Inc." *DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-10165-EFH (D. Mass. Sept. 14, 2004) (citing

WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1361 (Fed. Cir. 1999)). In denying Medtronic's renewed motion for JMOL on the subject of lost profit damages, the court noted that DePuy "introduced extensive evidence that DePuy had an exclusive license to the patent in suit as of January 23, 1998." *DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 01-10165-EFH (D. Mass. Feb. 15, 2005). Thus, the court ultimately concluded that DePuy was an exclusive licensee as of January 1998.

We must therefore examine the 1993 Technology Agreement to determine if it supports the conclusion that DePuy was an exclusive licensee to the '678 patent under its terms.

> Determining whether a licensee is an exclusive licensee or a bare licensee is a question of ascertaining the intent of the parties to the license as manifested by the terms of their agreement and examining the substance of the grant. The use of the word "exclusive" is not controlling; what matters is the substance of the arrangement. Because patent rights are rights to "exclude others," a licensee is an exclusive licensee only if the patentee has promised, expressly or impliedly, that "others shall be excluded from practicing the invention" within the field covered by the license. Put another way, an exclusive license is "a license to practice the invention accompanied by the patent owner's promise that others shall be excluded from practicing it within the field of use wherein the licensee is given leave."

Textile Prods. v. Mead Corp., 134 F.3d 1481, 1484 (Fed. Cir. 1998)(internal citations omitted).

The 1993 Technology Agreement provides that it shall be construed in accordance with Indiana law. Indiana follows the "four corners rule" of contract interpretation in which courts

do not look beyond the instrument in question to determine the parties' intent if the terms of the instrument are unambiguous. *Schmidt v. Schmidt*, 812 N.E.2d 1074, 1080 (Ind. Ct. App. 2004); *see also Univ. of S. Ind. Found. v. Baker*, 843 N.E.2d 528, 532 (Ind. 2006). "The terms of a contract are ambiguous only when reasonably intelligent persons would honestly differ as to the meaning of those terms." *Schmidt*, 812 N.E.2d at 1080; *see also Baker*, 843 N.E.2d at 532.

The terms of the 1993 Technology Agreement unambiguously provide an exclusive license to DePuy Spine for all of Biedermann Motech's current and future knowledge, techniques, processes, data designs, prints, drawings, specifications, procedures and other information relating to the manufacture of any product for use in the treatment of the human spine. In January 1998, Biedermann Motech acquired the '678 patent, which covers a particular design of pedicle screw for use in the treatment of the human spine. It follows that in 1998, when Biedermann Motech acquired the '678 patent, it acquired the design of the products covered by that patent as well. That design is a "future" design under the express terms of the 1993 Technology Agreement and provides a basis for the jury's lost profit award.

The terms of the 1993 and 1999 Exclusive License Agreements do not affect this conclusion. First, the 1993 Exclusive License Agreement is a license between Ort-Med, the licensor, and DePuy Spine, the licensee. Ort-Med never was-nor became-the owner of the '678 patent. Thus, the 1993 Exclusive License Agreement is not relevant to any determination of rights as between Biedermann Motech and DePuy Spine. Second, the 1999 Exclusive License Agreement was entered into on August 31, 1999; it is thus not relevant to the rights that were created between the parties by the 1993 Technology Agreement entered into on February 4, 1993. Therefore, we conclude that DePuy was entitled to lost profit

damages prior to August 31, 1999, and the court did not err in denying Medtronic's motion for JMOL on this issue.

CONCLUSION

Because the district court erred in construing the scope of the "hollow spherically- shaped portion" in the '678 patent to exclude the edge thereof, and because the court erred in limiting application of the doctrine of equivalents, we reverse the district court's summary judgment of non-infringement under the doctrine of equivalents on the Vertex® model and remand for further proceedings. We affirm the district court's grant of summary judgment of no literal infringement for the Vertex® model.

Because we conclude that the bottom-loaded screw models lack the "opening" limitation as a matter of law, we affirm the district court's grant of summary judgment of non-infringement for the bottom-loaded screw models.

Because the jury verdict finding that the MAS model infringed the '678 patent under the doctrine of equivalents was supported by substantial evidence and because the theory of equivalence was not legally insufficient, we hold that the district did not err in denying Medtronic's motion for JMOL of non-infringement. Because the district court correctly determined that DePuy became an exclusive licensee of the '678 patent prior to August 31, 1999, the district court did not err in denying Medtronic's motion for JMOL to preclude an award of lost profit damages prior to that date. We therefore affirm the jury verdict and damages award on the MAS model.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED.

COSTS

Costs to DePuy.

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

05-1311, -1335

DEPUY SPINE, INC. (formerly known as Depuy Acromed, Inc.) and BIEDERMANN MOTECH GMBH,
Plaintiffs-Appellants,

V.

MEDTRONIC SOFAMOR DANEK, INC. (formerly known as Sofamor Danek Group, Inc.) and

MEDTRONIC SOFAMOR DANEK USA, INC.,
Defendants-Cross Appellants.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Cross-Appellant, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on January 4, 2007.

Circuit Judge Dyk did not participate in the vote.

FOR THE COURT,
/s/ Jan Horbaly
Clerk

Dated: 12/28/2006

cc: Calvin P. Griffith
Dirk D. Thomas

DEPUY SPINE V MEDTRONIC SOFAMOR, 2005-1311, -1335 (DCT -01-CV-10165)

FILED U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT DEC 28 2006

APPENDIX C

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

DEPUY ACROMED, INC. and BIEDERMANN MOTECH GmbH, Plaintiffs

V.

MEDTRONIC SOFAMOR DANEK, INC., f/k/a SOFAMOR DANEK GROUP, INC., and MEDTRONIC SOFAMOR DANEK USA. INC., Defendants.

CIVIL ACTION NO. 01-10165-EFH

MEMORANDUM AND ORDER
April 14, 2003

HARRINGTON, S.D.J.

Defendants Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc.'s ("Medtronic") Motion for Summary Judgment of Patent Non-Infringement for Failure to Meet the "Compression Member" Claim Limitation (docket No. 104, item 1) and Medtronic's Motion for Partial Summary Judgment of Patent Non-Infringement Concerning Their Top-Assembled Pedicle Screws for Failure to Meet the "Hollow Spherically-Shaped Portion" Claim Limitation (docket No. 104, item 3) are denied.

Also, Plaintiffs Depuy Acromed, Inc. and Biedermann Motech GmbH's ("Acromed") Motion for Partial Summary

Judgment on Defendants' Counterclaim for Inequitable Conduct (docket No. 109) is denied.

Medtronic's Motion for Partial Summary Judgment of Patent Non-Infringement Concerning Their Bottom-Assembled Pedicle Screws Based Upon the Claim Elements "Opening" and "Bore" (docket No. 104, item 2) is granted.

The Court concludes that Medtronic's so-called "bottom-assembled screws" do not infringe the limitation in claim 1 of United States Patent 5,207,678 (the '678 patent) which reads ". . . the receiver chamber (7) having at one end thereof a bore (8) for passing the threaded shaft portion (3) therethrough . . . [and] an opening being provided opposite said bore (8) for inserting said screw (1). . . ." In particular, the defendant's bottom-assembled screws, the M8, M10, and Sextant models, lack ". . . the receiver chamber (7) having at one end thereof a bore (8) for passing the threaded shaft portion (3) therethrough."

Whereas the '678 patent describes a system where the screw is inserted shaft first through an opening at the top of the receiver member, Medtronic's bottom-assembled screws are placed into the receiver member head first, from the bottom. The threaded shaft remains outside the receiver member. Medtronic's pre-assembly process involves passing the threaded screw shaft through the center of a "snap ring," placing an additional component known as a "crow" on top of the screw head, and lifting these items into the bottom of the receiver member. The snap ring then locks the screw in place by "snapping" into a groove cut into the bottom of the inner surface of the receiver member. It is important to the Court's conclusion that claim 1 requires the bore, through which the threaded shaft of the screw must pass, to be part of the receiver chamber, which, in turn, is located within the receiver member. The snap ring, on the other hand, which Plaintiffs Acromed argue constitutes the bore in the allegedly

infringing devices, is a distinct item that is not found in the receiver chamber and, in fact, is not part of the receiver member at all when the threaded screw shaft is passed through it. Because Medtronic's bottom-assembled screws do not embody this limitation, they do not literally infringe claim 1. See e.g., Carroll Touch. Inc. v. Electro Mech. Sys.. Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993) ("A claim covers an accused device if the device embodies every limitation of the claim,. . ."); London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538-39 (Fed. Cir, 1991); Lemelson v. United States, 752 F.2d 1538, 155 1 (Fed. Cir. 1985). Nor can infringement be found through application of the doctrine of equivalents. "[T]he doctrine of equivalents cannot be used to vitiate an element from the claim in its entirety." K-2 Corp. v. Salomon. S.A., 191 F.3d 1356, 1367 (Fed. Cir. 1999) (citing Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997); Tronzo v. Biomet. Inc., 156 F.3d 1154, 1160, (Fed.Cir.1998)). As Medtronic's snap ring is a separate item and its pedicle screws enter the receiver members head first from the bottom, a jury could not find the M8, M10, and Sextant are substantially equivalent to the patented invention without vitiating the element of claim 1 that calls for a bore that is part of a receiver chamber and through which the threaded shaft portion of the screw is passed. *Id.*

SO ORDERED.

/s/ EDWARD F. HARRINGTON
United States Senior District Judge

APPENDIX D

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

DEPUY ACROMED, INC. and BIEDERMANN MOTECH GmbH,
Plaintiffs

V.

MEDTRONIC SOFAMOR DANEK, INC., f/k/a SOFAMQR DANEK.GROUP, INC., and MEDTRONIC SOFAMOR DANEK USA. INC.,
Defendants.

CIVIL ACTION NO. 01-10165-EFH

MEMORANDUM AND ORDER
February 24, 2004

HARRINGTON, S.D.J.

For the reasons set forth below, Defendants Medtronic Sofamor Danek Inc, and Medtronic Sofamor Danek USA, Inc.'s ("Medtronic' Motion for Summary Judgment of Non-Infringement Concerning Their Vertex Screw is allowed.

Plaintiffs Depuy Acromed, Inc. and Biedermann Motech GMBH ("Acromed") claim that the Medtronic's Vertex Screw infringes U.S. Patent No. 5,207,678 ("the '678 patent"). The '678 patent discloses a pedicle screw with a receiver member that contains an "inner hollow spherically-shaped portion" for receiving the spherical head of a pedicle

screw.[2] In its Markman Order of October 27, 2003, this Court ruled that the claim term "spherically-shaped" meant that the shape of the inner hollow portion of the receiver member must be "approximately spherical, such as a globe or basketball." Further, this Court ruled that the spherical shape must exist before the screw head presses into the receiver member.'

The present motion requires the Court to determine whether there is any genuine issue of material fact as to infringement by the Vertex Screw; put differently, this Court may grant Medtronic's motion if Acromed's "proof is deficient in meeting an essential part of the legal standard for infringement." Johnston v IVAC Corp., 885 F.2d 1577 (Fed. Cir. 1989). Infringement may occur literally or under the Doctrine of Equivalents. Literal infringement of a patent claim occurs "when every limitation recited in the claim appears in the accused device, i.e., when 'the properly construed claim, reads on the accused device exactly.'" KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1358 (Fed. Cir. 2000)(citation omitted). Infringement under the Doctrine of Equivalents occurs when there are only "insubstantial differences" between a claim element and the corresponding aspect of the accused device. Allen Eng'g Corp. v. Bartell Indus, Inc., 299 F.3d 1336, 1345 (Fed. Cir. 2002).

Medtronic's Vertex Screw does not literally infringe the '678 patent. The receiver member component of the Vertex Screw does not have an inner hollow space that is "spherically-shaped" as defined by this Court, as the '678 patent requires. Instead, the inner hollow space has lower chamber walls in a conical shape that intersect with cylindrical, vertical side walls at an angle of 118 [degrees]. See Defendants' Memorandum in Support of their Motion for Summary

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[2] For further background about the '678 patent, see this Court's Markman Order of October 27, 2003.

Judgment of Non-Infringement Concerning the Vertex Screw (Def. Mem.) at 3, 4 (images illustrating shape of the Vertex Screw receiver member).

Acromed replies that the lower edge of the receiver member of the Vertex Screw is a spherically-shaped portion. See Plaintiffs' Opposition to Defendants' Renewed Motion for Summary Judgment of Non-Infringement Concerning Their Vertex Screw (Pl. Opp.) at 8-10. However, the shape that Acromed describes in its brief and accompanying illustrations is circular, not spherical.[3] In an attempt to establish that this shape is spherical, Acromed presents a photomicrograph of a cross-section of the Vertex receiver. See Pl. Opp. at 11. The Court does not find this evidence sufficient to create a genuine issue of material fact for two reasons. First, the shape disclosed by the photomicrograph is angular rather than spherical. Compare Defendants' Reply Memorandum (Def. Rep.) at 8 with Pl. Opp. at 11. Second, even if a portion of the shape disclosed by the photomicrograph is spherical, this spherically-shaped portion does not actually come into contact with the head of the screw, as required by the '678 patent. Pl. Opp. at 11 (illustration); '678 patent, col. 4, line 23-24 (requiring that head of the pedicle screw must be "pressed against the hollow spherically-shaped portion").

The Vertex Screw also does not infringe under the Doctrine of Equivalents. Under this doctrine, the Court must focus on each limitation individually, rather than considering the accused device as a whole. Allen Eng'g Corp., 229 F.3d at

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[3] As the American Heritage Dictionary, Fourth Edition, makes clear, a sphere is a "three-dimensional surface, all points of which are equidistant from a fixed point." A circle, on the other hand, is a "plane curve everywhere equidistant from a given fixed point, the center." While a sphere or spherical portion has the three-dimensional rounded shape of a globe or basketball, the Vertex Screw receiver member does not have an appreciably three-dimensional shape.

1345. Thus, this Court must determine whether the receiver member of the Vertex Screw has the equivalent of an inner, hollow, spherically-shaped portion.

Two rules guide the Court's inquiry. The first is the All Elements Rule. Under this rule, the Court must be "specially vigilant against allowing the concept of equivalence to eliminate any claim limitations completely." Id. The second rule is known as the Function/Way/Result Test. Under this test, the accused device must do "substantially the same thing in substantially the same way to get substantially the same result as the claim limitation" in order to me a patent under the Doctrine of Equivalents. Id. (citations omitted). Medtronic argues that the All Elements Rule is applicable and the Function/Way/Result test is inapplicable; Acromed argues just the opposite. In the Court's view, both rules support the conclusion that the Vertex Screw does not infringe the '678 patent under the Doctrine of Equivalents.

Under the "All Elements Rule," the Court cannot find that the cylindrical-conical shape of its receiver member is equivalent to the spherically-shaped portion disclosed in the '678 patent. In Tronzo v. Biomet, Inc., 156 F.3d 1154 (Fed. Cir. 1998), the Federal Circuit considered a patent and accused device relating to hip implants. The Court ultimately held that the hemispherically shaped device could not infringe a "generally conical" claim limitation because, in light of the slightly different forces produced by the different shapes, permitting this equivalence would effectively read the "generally conical" requirement out of the claim. Tronzo, 156 F.3d at 1160. Likewise, in the present case, the cylindrical- conical shape of the Vertex Screw receiver member cannot infringe the '678 patent without reading out of the claim the express requirement that the screw head be "pressed against the

hollow, spherically-shaped portion."[4]

The Function/Way/Result Test also supports the Court's conclusion that the Vertex Screw mot infringe the '678 patent under the Doctrine of Equivalents. The Vertex Screw does not do "substantially the same thing" as the screw disclosed in the '678 patent. The '678 patent discloses a screw head which creates a lock with the receiver member by pressing against an inner surface that is almost the same shape as the screw head. The Vertex Screw head and receiver member instead are joined over a much smaller area; the screw head is merely pressed against an edge or lip on the receiver member. See Def Mem. at 4 (illustration). Thus, the two screws operate in a different way, and there can be no equivalence under the Function/Way/Result Test.

Defendants' Motion for Motion for Summary Judgment of Non-Infringement Concerning Their Vertex Screw is allowed.

SO ORDERED.
/s/ EDWARD F. HARRINGTON
United States Senior District Judge

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[4] Acromed alerts the Court that the Federal Circuit has counseled against a broad reading of Tronzo. The Federal Circuit warns that Tronzo "does not stand for the proposition that a claim limitation describing a specific shape of a claimed structure cannot be infringed under the doctrine of equivalents by a differently shaped structure." Optical Disc Corp. v. Del Mar Avionics, 208 F.3d 1324, 1337 (Fed. Cir. 2000). The Court does not read Tronzo for the broad principle that differently shaped structures can never be equivalent. Instead, the Court reads Tronzo as an application of "conventional doctrine of equivalents law, including the 'all elements' or 'all limitations' rule." Optical Disc Corp., 203 F.3d at 1337. In the present case, permitting the cylindrical-conical shape of the Vertex Screw to be considered equivalent to the spherical shape required by the '678 patent vitiates the '678 patent requirement that the spherically-shaped head of the pedicle screw be pressed against an inner, hollow, spherically- shaped portion of the receiver member.

United States District Court
District of Massachusetts

Notice of Electronic Filing

The following transaction was received from Holahan, Sandra entered on 2/27/2004 at 10:02 AM EST and filed on 2/24/2004
Case Name: DePuy AcroMed, Inc., et a1 v. Mcdtronic Sofamor Danek, et al
Case Number: 1:01-cv-10165 Filer:
Document Number:

Docket Text: Judge Edward F. Harrington: ELECTRONIC ORDER entered granting [170] Motion for Leave to File memorandum in reply. MOTlON ALLOWED. cc/cl (Holahan, Sandra)

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APPENDIX E

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

DEPUY ACROMED, INC. and
BIEDERMANN MOTECH GmbH,
Plaintiffs

V.

MEDTRONIC SOFAMOR DANEK, INC.,
f/k/a SOFAMOR DANEK GROUP, INC.,
and MEDTRONIC SOFAMOR DANEK USA. INC.,
Defendants.

CIVIL ACTION NO.
01-10165-EFH

MEMORANDUM AND ORDER
October 27, 2003

HARRINGTON, S.D.J.

On May 4, 1993, the United States Patent and Trademark Office issued United States Patent No. 5,207,678 ("the '678 patent"), titled "Pedicle Screw and Receiver Member Therefore." Plaintiffs DePuy Acromed, Inc. and Biedermann Motech GmBH ("Acromed") are the exclusive licensee and assignee, respectively, of the '678 patent. On January 26, 2001, plaintiffs commenced an infringement action against Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc. ("Medtronic") for the infringement of the '678 patent.

After this Court ruled on various summary judgment motions of the parties on April 14, 2003, Acromed moved for

construction of three disputed terms in the claims of the '678 patent. These terms were briefed by the parties, and a Markman hearing was held on September 24, 2003. Having considered the written and oral arguments and evidence offered by the parties, the Court now construes three phases from Claim 1 of the '678 patent.

I. BACKGROUND

The '678 patent discloses a pedicle screw and receiver member. Pedicle screws are implanted in human vertebra during surgery. The head of each pedicle screw is connected to a receiver member, and a threaded rod then connects the receiver members of several screws. Surgeons use this network of screws, receiver members, and rods to stabilize spinal column segments. The invention disclosed in the '678 patent permits screws of various sizes to be used with a uniform receiver member. Thus, doctors do not need to stock unique receiver members for each size screw they might use, and stocking costs are consequently reduced.

Claim 1 is the only independent claim of the '678 patent. The parties ask the Court to construe terms relating to three aspects of the connection between the screw head and the receiver member. In pertinent part, and with the claims to be construed set forth in bold, Claim 1 discloses a

> [d]evice for stabilizing spinal segments, comprising a pedicle screw (1) having a threaded shaft portion (3) and a spherically-shaped head (4) at the end of said threaded shaft portion, a receiver member (5) **flexibly connected** to said head (4), said receiver member being provided with. . . an **inner hollow spherically-shaped portion** *(9)* for receiving the head (4) of said screw (1), an opening (10) being provided . . . for inserting said screw (1), said device further comprising a **compression member** *(18)* for exerting a force onto

said head (4) such that said head is pressed against **the hollow spherically-shaped portion (9).**

II. ANALYSIS

Patent claims are to be construed by the Court as a matter of law. Allen Engineering Corp. v. Bartell Industries, Inc., 299 F.3d 1336, 1344 (Fed. Cir. 2002) (citing Markman v. Westview Instruments. Inc., 52 F.3d 967, 979 (Fed. Cir. 5995) (en banc), aff'd 517 U.S. 370 (1996)). In construing the claims, the Court looks first to the intrinsic evidence, which includes the language of the claims, the specification, and the prosecution history if it is in evidence. Altiris Inc. v. Symantec Corp., 318 F.3d 1363,1375 (Fed. Cir. 2003); Vitronics Corp. v. Conceptronic. Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). If analysis of intrinsic evidence is sufficient to resolve ambiguities in the meaning of a disputed claim term, as it is here, reliance on extrinsic evidence is improper. Vitronics, 90 F.3d at 1583.

In considering the intrinsic evidence, the Court looks first to the language of the claim itself. Under the patent statute, the claims must "particularly point out and distinctly claim the subject matter which the applicant regards as his invention." 35.U.S.C. § 112 ¶ 2. Thus, in construing a claim, there is a "heavy presumption" that terms used "have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (2002)(citing cases). The Federal Circuit instructs that claim terms should be given their "full meaning" and notes that dictionaries, encyclopedias, and treatises are particularly useful because they are "objective resources... not colored by the motives of the parties and not inspired by litigation." Id. at 1203.

A. Inner Hollow Spherically-Shaped Portion

Claim 1 of the '678 patent describes the receiver member as having an "inner hollow spherically-shaped portion for receiving the head" of the pedicle screw. Claim 1 describes the head of the pedicle screw as being "spherically-shaped." As the briefs and oral argument made clear, the principal dispute centers on the meaning of "spherically-shaped" as it relates to the hollow inner portion of the receiver member.

Plaintiffs contend that the term "spherically-shaped" should be interpreted to mean "a concave, three-dimensional surface that could be shaped by a sphere or by a segment of a sphere, or by an object approximating either of those things." Pl. Opp. Br. at 14. At oral argument, plaintiffs' counsel stated this definition more succinctly as "approximately spherical," noting that the American Heritage Dictionary, third edition, defines "spherical" as "[h]aving a shape approximating that of a sphere."

Defendants, on the other hand, urge that the term "spherically-shaped" requires that the inner hollow portion of the receiver member be "concave and shaped like a portion of a sphere." Defendants' Claim Construction Memorandum (Def. Cl. Const. Mem.) at 1. They observe that "spherically" is the adverb form of "sphere," which is defined by Webster's New Twentieth Century Dictionary, second edition, as "any round body or figure having the surface equally distant from the center at all points; a globe; a ball."[5] *Id.* at 9. However, at oral argument and in memoranda to this Court, defendants "concede[ ] that a shape can still be described as 'spherical' even if it is not a perfect sphere." Def.'s Reply Mem. at 5.

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[5] Defendants also cite the more technical definition of a sphere found in the McGraw-Hill Dictionary of Scientific and Technical Terms, 4th. edition. Def. Cl. Const. Mem. at 9 n.4.

Alternatively, defendants argue, if the term "spherically-shaped" does not require a perfect geometric sphere, it should be construed to require that the inner hollow portion be "sufficiently close so as to match or mate with the spherical screw head that is 'pressed against' it." Def. Cl. Const. Mem. at 1. At oral argument, counsel for defendants agreed that "approximately spherical" conveyed accurately the degree of precision required. Further, counsel for both parties agreed that providing an example such as a globe or basketball would help the jury understand the level of precision that this definition would require.

For reasons set forth below, consistent with the agreement of counsel, the Court construes "spherically-shaped" to mean "approximately spherical, such as a globe or basketball." Further, the Court rules that the inner hollow spherically-shaped portion may not be formed by the head of the pedicle screw; rather, the spherical shape must exist before the screw head is inserted into the receiver member.

The Court bases its ruling that "approximately spherical" is the correct construction of "spherically-shaped" on the language of the claim.[6] Defendants cite a dictionary definition which requires a perfect sphere while plaintiffs cite a dictionary definition approving "approximately spherical."

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[6] The Court also finds support for its construction in the specification. The specification employs the term "spherical segment-shaped," which appears to convey a more precisely spherical shape than the claim term "spherically shaped." The Court will not restrict the meaning of the claim term by reading the "segment" limitation from the specification into the claim. See Texas Digital, 308 F.3d at 1205 (noting the Federal Circuit's prohibition on "reading limitations from the specification into the claims"); Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1326 (Fed. Cir. 2002) ("limitations from the specification are not to be read into the claims") (citing Comark Communications, Inc, v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998)).

When claim terms have more than one dictionary definition, courts consult the intrinsic record to determine which definition "is most consistent with the use of the words by the inventor." Texas Digital 308 F.3d at 1203. If more than one definition proves consistent with the use of the words in the intrinsic record, the claim term "may be construed to encompass all such consistent meanings." Id. Defendants have not cited any evidence from the intrinsic record to suggest that the broader definition, "approximately spherical," is not appropriate. At most, defendants point out that plaintiff could have described the inner hollow space as "rounded" or "approximately spherical." Def. Cl. Const. Mem. at 9. However, plaintiffs correctly reply that there was no need to so qualify the term "spherical" when the American Heritage Dictionary definition cited above defines the term spherical as "[h]aving a shape approximating that of a sphere."[7]

A final dispute the construction of "inner hollow spherically-shaped portion" remains. Plaintiffs' proposed construction describes "a concave, three-dimensional surface that could be shaped by a sphere." Pl. Op. Br. at 14 (emphasis added). Defendants urge that the language of the claim does not allow "an area [to be] formed in the receiver chamber by . . . deformation caused by the pressing of the [spherical] head of

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[7] The Court has also considered formulations offered by the defendants in their briefs and at oral argument. The Court does not perceive a meaningful difference between "approximately spherical" and "sufficiently close so as to match or mate with the spherical screw head that is 'pressed against' it," or defendants' other formulations. Further, to the extent that this formulation conveys something closer to perfectly spherical than "approximately spherical," it improperly narrows the ordinary meaning of the claim term as found in the dictionary definition "approximately spherical." Nonetheless, to make clear the shape and degree of precision contemplated by "approximately spherical," the Court includes the examples "globe" and "basketball" in its construction. Counsel for defendants suggested these terms at oral argument, and plaintiffs' counsel agreed that they would be helpful to the jury.

the screw against the receiver member." Def Cl. Const. Mem. at 13. Put differently, defendants contend that the inner, hollow, spherically-shaped portion must exist before the screw is inserted into the receiver member. For reasons set forth below, the Court agrees.

The language of Claim 1 envisions a "receiver member (5). . . being provided with. . . an inner hollow spherically-shaped portion (9) for receiving the head (4) of said screw (l)." '678 patent, col. 4, lns. 12-20. In the court's view, in order for the inner hollow spherically-shaped portion to "receive" the head of the screw, it must be spherically-shaped before the screw head is inserted into it, Language later in the claim cob this view; the claim also envisions a "compression member (1 8) for exerting a force onto said head (4) such that said head is pressed against the hollow spherically-shaped portion (9)." '678 patent, col. 4, lns. 22-24 (emphasis added). This description also implies that the spherically-shaped portion exists before the screw head is pressed into it.

The Court's conclusion that the spherically-shaped portion of the receiver member must exist before the screw head is pressed into it is reinforced by examining Waner v. Ford Motor Co., 331 F.3d 85 1 (Fed. Cir. 2003). The patent at issue in Waner claimed a fender liner to be used on a truck "comprising an elongated flat panel . . . with an inboard side flange, said flat panel . . . suited to be installed inside the fader." Waner. 331 F.3d at 853-54. The court held that this language required that the flange exist prior to installation, because the patent described "said flat panel [i.e., with a flange]. . . suited to be installed." Waner, 331 F.3d at 855. The court further noted that "nothing in the specification or the drawings suggests the flange need not exist prior to installation" Id. Likewise, the language of the '678 patent contains a reference to "the hollow spherically-shaped portion (9)," against which the screw head is to be pressed. In addition, nothing in the specification or drawings of the '678

patent suggests that the spherically-shaped portion need not exist prior to installation. Plaintiffs contend that the patent at issue in Waner describes only the flat panel whereas the '678 patent describes a two-piece assembly (the screw head and the receiver member), but the Court does not find this difference to be significant. The court in Waner based its holding on the language of the patent, not on the fact that the device was intended to be installed into something else. Likewise, this Court bases its construction primarily on the language of the '678 patent.

B. Flexibly Connected

Claim 1 of the '678 patent describes the receiver member as "flexibly connected to said head (4)" (i.e., the spherically-shaped head of the pedicle screw). '678 patent, col. 4, lns. 12-13. Plaintiffs contend that this language refers to the polyaxial nature of the screw, that is, the ability of the screw to articulate or bend relative to the receiver member. Thus, plaintiffs request a claim construction which requires "that the screw head and receiver member [be] joined together in a flexible manner such that the screw assembly has the ability to bend at the connection between the screw head and the receiver." Pl. Op. Br. at 7. Defendants urge that the flexible connection refers to the ability of the sidewalls of the receiver member to bend slightly. Their proffered construction would require that "the sidewalls of the receiver member yield or bend inwardly to fasten and lock" the screw head within the receiver member. Def. Cl. Const. Mem. at 2. For reasons set forth below, the Court adopts plaintiffs' proposed construction.

Because the patentee has not acted as its own lexicographer and set forth a special definition of "flexibly connected," the "ordinary and customary meaning" of these words is presumed to apply. See Vitronics, 90 F.3d at 1582. The parties agree that Webster's suitably defines the terms

"flexibly" and "connected." Def. Cl. Constr. Mem at 14; Pl. Op. Br. at 7-8. "Flexibly" is the adverb form of "flexible," and is thus defined as "in a flexible manner." Webster's New Twentieth Century Dictionary, second edition. "Flexible" is defined as "1. that may be bent; capable of being turned or forced from a straight line or form without breaking; pliant; yielding to pressure; not stiff" Id. "Connected" is defined as "joined together; fastened." Id. The present dispute is thus not so much about the ordinary and customary meanings of these words as it is about the meanings applied to the particular device disclosed in the '678 patent.

The context of these words aids in their interpretation. The '678 patent discloses a "receiver member flexibly connected to said head." "Connected" is used as an adjective modifying "receiver member," and "flexibly" as an adverb modifying "connected." Thus, the receiver member must be connected or joined to the spherically-shaped head of the screw, and that connection must be "flexible," or able to bend. In the Court's view, this is the most natural reading of the language, the reading that a person of ordinary skill in the art would adopt. This reading comports with plaintiffs' view that the connection between screw and member must be flexible so that the screw head pivots within the receiver member. Defendants, on the other hand, contend that the receiver member itself must connect flexibly by having sidewalls which yield inwardly around the head of the screw. The Court believes that defendants' reading parses the connection between receiver and screw more finely than the language of the claim will allow. Further, if the Court were to accept defendants' construction, then no limitation in Claim 1 of the '678 patent would disclose that the screw was polyaxial in nature.

Reference to the specification and to Claim 2 of the '678 patent confirms the Court's view that plaintiffs have the better argument. The specification in its very first sentence echoes

the language of the claim by describing a "receiver member . . . for a hinged connection of a screw . . . with a rod."[8] '678 patent, col. 1, lns. 5-8. This language makes clear that the receiver member accomplishes a hinged connection which allows the screw to pivot into various positions, that is, to be polyaxial. Further, Webster's defines "hinged" as "attach[ed] by or furnished with hinges;" a 'hinge" is defined as "a jointed or flexible device on which a door, lid, or other swinging part turns." Thus, in the Court's view, given that hinged and flexible are in some respects synonymous, it is appropriate to interpret the term "flexibly connected' in light of the term in the specification, 'hingedly connected."

Defendants urge that the Court look to a different portion of the specification to illuminate "flexibly connected." The specification states that "[o]wing to the slits 17 and 23 [in the receiver member] the cylindrical wall of the housing 6 can slightly yield such that the clamping force acting onto the head is increased." '678 patent, col. 3, lns. 53-56. Defendants urge that the word "yield," which appears in the Webster's definition of "flexible," provides a verbal link between that claim term and this statement in the specification. Def. Reply Mem. at 10. Thus, in the defendants' view, the receiver member itself is flexible in its connection to the head of the screw.

The Court does not make this link, however, for several reasons. First, the connection between the receiver member and the head of the screw must be flexible under the language of Claim 1; defendants' argument contemplates that the receiver member itself must be flexible. The sides of the receiver member may well yield, but once they do, the connection they form with the head of the pedicle screw is rigid, not flexible. The flexible connection is achieved

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[8] The Abstract begins similarly: "A receiver member is provided for hingedly connecting a screw ... and a rod."

between the receiver member and the screw by means of the spherically-shaped screw head fitting in to the inner, hollow spherically-shaped portion of the receiver member. Second, the Court believes that the term "hingedly connected" echoes the term "flexibly connected" more closely and thus, as set forth above, more clearly illuminates the nature of the connection between the receiver member and the head of the pedicle screw. Finally, the slits referred to (reference numbers 17 and 23) are not set forth at all in Claim 1. In fact, they appear only in Claim 2, which requires that there be "at least one slit (17)." '678 patent, col. 4, lns. 27-28. Claim 2 has not been asserted in this case. Further, the specification envisions that the inward yielding is to be accomplished by means of side-tightening locking nuts which again do not appear in Claim 1 and only appear in Claim 2. Thus, defendants appear to be asking the Court to interpret the words "flexibly connected" which are found in Claim 1, in light of the requirements of Claim 2, namely, slits marked 17 and 23 and locking nuts marked 24 and 25. The Court refuses the invitation to constrict the meaning of "flexibly connected" in this way.

Defendants also argue that the prosecution history of the '678 patent supports their view that "flexibly connected' refers to the inward yielding of the sides of the receiver member around the head of the pedicle screw. The plaintiffs' '678 patent application as originally filed "describ[es] a pedicle screw device where the screw head was 'jointly connected' to the receiver member." Def Cl. Constr. Mem. at 16. This original application was denied as being anticipated by earlier patents. Appendix to Def., Cl. Constr. Mem., Tab 7, pages 3-4. Prior to the rejection, plaintiffs submitted a preliminary amendment, including claims employing the term "flexibly connected;" these claims were subsequently resubmitted and issued as the '678 patent. Pl. Op. Br. at 12.

Defendants, derive great significance from the shift from the term "jointly connected" to the term "flexibly connected." They argue that the initial application was rejected because the term "jointly connected" refers to the polyaxial motion of the pedicle screw and thus was anticipated by a prior art device, patented in the European Union under EP 0 242 708. In their view, "flexibly connected" distinguishes the '678 patent as finally issued from the initial application (and thus also from the EP patent application) because "flexibly connected" refers not to the polyaxial nature of the screw, but to the inward yielding of the receiver member sidewalls, which defendants purport is the actual difference between the '678 device and the EP device.

However, the EP was not the only prior art device the patent examiner cited in rejecting the original '678 patent application. In fact, three prior art devices are cited in the examiner's rejection. Nor is there any indication in the record that the term "jointly connected" caused the patent examiner to reject the original '678 application. In fact, there are numerous changes in wording between the original '678 patent claims and the claims that ultimately issued. Even if the Court were to agree that "flexibly connected" must be construed differently from "jointly connected," the Court has seen no evidence which would compel the conclusion that these two terms differ in the particular manner urged by defendants or that this difference caused the rejection of the initial application and the approval of the revised claims of the '678 patent.[9]

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[9] Defendants cite CAE Screenplates, Inc. v. Heinrich Fielder GMBH & Co., 224 F.3d 1308, 1317 (Fed. Cir. 2000) for the proposition that "in the absence of any evidence to the contrary, [a court] should presume that the use of . . . different terms in the claims connotes different meanings." Def. Cl. Constr. Mem. at 17. However, in CAE Sreenplates, the court characterized the intrinsic evidence, including prosecution history, as "overwhelming[ly] clear;" there is no such clarity in the present case.

Thus, the Court construes "flexibly connected" to require that the screw head and receiver member [be] joined together in a flexible manner such that the screw assembly has the ability to bend at the connection between the screw head and the receiver.

C. Compression Member

Claim 1 of the '678 patent also discloses a "compression member (18) for exerting a force onto said head (4) such that said head is pressed against the hollow spherically-shaped portion." Defendants argue that this language should be construed as a "means plus function" limitation under 35 U.S.C. 9 112 ¶ 6. This construction would "limit this claim element to the single embodiment of the compression member disclosed in the specification and structural equivalents thereof." Def. Cl. Constr. Mem. at 2. More particularly, defendants would limit the meaning of "compression member" to "the unique type of cylindrical compression member having two offset yielding slits (23) and two slits for receiving a threaded rod (21, 23) disclosed in the figures and specifications of the '678 patent and structural equivalents thereof." Id. at 20. Plaintiffs, on the other hand, argue that "compression member'' has a generally understood meaning to people of skill in the art and urge the Court to construe "compression member" as requiring only "an intermediate piece (or member) that applies a compression force to the head of the screw." Pl. Op. Br. at 19. For reasons set forth below, the Court adopts the plaintiffs' construction of the term "compression member."

The patent statute permits an element of a claim to be "expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof." 35 U.S.C. § 112 ¶ 6. Claims expressed in this manner are commonly said to be written in a "means plus function" format. The statute specifies that claims written in

means-plus-function format "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." Id. The question whether a claim is written in means-plus-function format is "a matter of claim construction and is thus a question of law." *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1360 (Fed. Cir. 2000).

When a claim element actually uses the word "means," courts apply a rebuttable presumption that § 112 ¶ 6 is invoked. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1369 (Fed. Cir. 2002); Personalized Media Communications, LLC v. Int'l Trade Comm'n 161 F.3d 696, 703-04 (Fed. Cir. 1998). Where, as here, the claim element does not use the word "means," courts presume that § 112 ¶ 6 does not apply. CCS Fitness, 288 F.3d at 1369. These presumptions may be rebutted; in deciding whether they are, courts consider whether "the claim as properly construed recites sufficiently definite structure" and thus avoids the 'means-plus-function" designation. Personalized Media, 161 F.3d at 704. Notably, the Federal Circuit has reminded courts that they need not find that a term conveys a "precise physical structure" to avoid the means-plus-function designation. Id. at 705. A term discloses "sufficiently definite structure" if it "convey[s] to one knowledgeable in the art a variety of structures." Id.

Defendants acknowledge that the '678 patent does not use the term "means," and thus agree that the Court should presume that § 112 ¶ 6 does not apply. Def. Cl. Const. Mem. at 18. Nonetheless, defendants argue that the presumption is rebutted because the term "compression member . . . does not recite any structure but merely recites its claimed function." *Id.* The Court disagrees, concluding that the term "compression member" when properly construed in context recites sufficient structure to escape the means-plus-function statutory scheme.

The Federal Circuit has construed the term "reciprocating member" in the context of a patent for an elliptical trainer as reciting sufficient structure to avoid the means-plus-function designation. See CCS Fitness, 288 F.3d at 1369-70. Because the context of stationary exercise devices is rather different from the context of pedicle screws, the specific result reached by the court in CCS Fitness is less helpful to the present case than is the court's method of analysis. The CCS Fitness court first considered what structures were revealed by technical and general dictionary definitions of "member," then the court considered what structure was suggested by the remaining claim limitations. Id. This Court follows that method in analyzing the present case.

First, dictionary definitions reveal that the term "compression member" has structural implications. Webster's defines "compression member" as "a structural member (as of a building or airplane) that is subjected to compressive stresses." Webster's Third New International Dictionary, 1986. Further, the McGraw-Hill Dictionary of Scientific and Technical Terms, 4th ed. 1989, defines "compression member" as a "beam or other structural member which is subject to compressive stress." These definitions provide examples of the structures a compression member might take in the contexts of buildings and airplanes; the Court believes that one skilled in the art of pedicle screws would understand what the corresponding structure of a compression member should be.

Further, the remaining limitations of Claim 1 of the '678 patent clarify the structure of the compression member. The compression member is to be placed inside the receiver member, located above the spherically-shaped head of the pedicle screw. '678 patent, col. 4, lns. 22-23. It must both fit inside the receiver member in the precisely-descried "receiver chamber" along with the head of the screw, and it must be of sufficient size to deliver force onto the head of the screw.

These limitations would convey to one skilled in the art what structure the compression member might take.

Defendants rely on Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206 (Fed. Cir. 1998). In Mas-Hamilton, the Federal Circuit considered the term "movable link member," an element in a patent for a high security electronic dial combination lock. Id. at 1214. The court found that although there was a presumption that means-plus-function did not apply, this presumption was rebutted because the term was defined only by functional language and the remaining claim limitations did not "provide *any* structure." Id. at 1215 (emphasis added).[10] However, the Mas-Hamilton case does not control the outcome here. In Mas-Hamilton, the court was faced with a functional definition and the absence of any structural language. Here, the term "compression member" is defined in the dictionary in terms that suggest structure, and the structure of the compression member is suggested by the requirements of the remaining claim limitations.

III. CONCLUSION

For the reasons set forth above, the Court construes "spherically-shaped" to mean "approximately spherical, such as a globe or basketball." The Court construes "flexibly connected" to require that the screw head and receiver member [be] joined together in a flexible manner such that the screw assembly has the ability to bend at the connection between the screw head and the receiver. Finally, the Court does not construe "compression member" as a means-plus-function claim limitation; instead, it construes "compression member" to require an intermediate piece (or member) that applies a compression force to the head of the screw.

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[10] The court also considered the term "lever moving element" and reached the same conclusion on a similar rationale. Id. at 1213-14.

SO ORDERED.
/s/ EDWARD F. HARRINGTON
United States Senior District Judge

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No. 06-1434

IN THE

Supreme Court of the United States

MEDTRONIC SOFAMOR DANEK, INC., F/K/A SOFAMOR DANEK GROUP, INC., and MEDTRONIC SOFAMOR DANEK USA, INC.,

Petitioners,

v.

DEPUY SPINE, INC., F/K/A DEPUY ACROMED, INC., and BIEDERMANN MOTECH GMBH,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit correctly reversed a grant of summary judgment and remanded this case for additional factfinding after concluding—based on the particular patent and prosecution history involved in this case, and on the plaintiffs' theory of equivalence—that the plaintiffs had raised genuine issues of material fact regarding whether the accused Vertex® devices are insubstantially different from those claimed in the patent in suit.

PARTIES TO THE PROCEEDINGS AND CORPORATE DISCLOSURE STATEMENT

Johnson & Johnson owns more than 10% of the stock of respondent DePuy Spine, Inc.

Respondent Biedermann Motech GMBH is privately held.

Respondents otherwise agree with petitioners' statement of the parties to the proceedings.

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BRIEF IN OPPOSITION

Respondents DePuy Spine, Inc. and Biedermann Motech GMBH respectfully request that the Court deny the petition for a writ of certiorari for four basic and fundamental reasons:

First, the question presented by the petition is so vague and unlimited that it neither provides the proper notice to respondents, nor aids the Court in framing the dispute.

Second, the "foreseeability test" now being urged upon this Court by petitioners—even aside from its stark inconsistency with established Supreme Court precedent—was never urged on the district court, never argued to the Court of Appeals panel, and not set forth in the petition for rehearing and rehearing *en banc*. As a result, the parties never had an opportunity to make a record on this issue, never had an opportunity to present arguments and authorities on the issue, and no federal court has yet been given the opportunity to rule on it.

Third, because the Court of Appeals remanded the case for a trial with respect to petitioners' Vertex® device, the case presently stands in an interlocutory posture, and petitioners have shown no exceptional or compelling reason for this Court to depart from its ordinary practices and entertain this petition.

Fourth, the decision below, rendered by a unanimous panel, with rehearing *en banc* summarily denied, represents a factbound application of established law, on which there is no conflict in decisions—either within or without the Federal Circuit.

REASONS FOR DENYING THE WRIT

1. Petitioners' "Question Presented" fails this Court's Rule 14.1(a). That rule requires a question presented to be "expressed concisely in relation to the circumstances of the case," and not "argumentative or repetitive." As this Court has explained, this rule serves two essential purposes: *One*,

it "provides the respondent with notice of the grounds upon which the petitioner is seeking certiorari, and enables the respondent to sharpen the arguments as to why certiorari should not be granted"; and *two*, it "assists the Court in selecting the cases in which certiorari will be granted," by identifying the specific "particularly important questions" and thus "enabling [the Court] to make efficient use of [its] resources." *Yee v. City of Escondido*, 503 U.S. 519, 535-36 (1992).

The "Question Presented" here (Pet. i)—which contains, in reality, two components—is not expressed "in relation to the circumstances of [this] case." Rather, as petitioners themselves admit, it is phrased initially as the "broad and general" question of whether "the Federal Circuit [has] properly and consistently balanced the public-notice function of patent claims . . . with the desire to protect patentees from unscrupulous copyists . . . ?" And if not, the question continues, "how can the analysis of patent infringement under the doctrine of equivalents be better crafted to achieve more consistent and predictable outcome [*sic*]?"

Neither component serves Rule 14.1(a)'s purposes. Instead, the question is styled as such a "broad and general" (and argumentative) policy issue that it could sweep almost every conceivable question related to patent infringement within its scope. That is undoubtedly why the Question Presented concludes with the grandiose claim that "[t]he answer to this question can affect virtually every issued U.S. patent and every U.S. patent infringement action, as well as any enterprise and member of the public affected by the grant of a U.S. patent."

As presented, this question would not serve the purpose of limning the scope of the briefing and argument in the event of plenary review. That in turn would "thwart" the "integrity of the process of certiorari." *See Taylor v. Freeland & Kronz*, 503 U.S. 638, 646 (1992). The inappropriate

question presented by petitioners is a sufficient reason, in and of itself, to deny certiorari.

2. Although the Question Presented makes no mention of it, the petition goes on to urge this Court to adopt a "foreseeability test," ostensibly crafted from the Court's last doctrine-of-equivalents case, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). Pet. 23-27. Petitioners waived this argument by failing to make it below and that argument contradicts this Court's decisions.

a. For one, petitioners never made this argument below. They urged no "foreseeability test" on the district court, nor on the Court of Appeals. The panel hearing the case did not decide it by considering and rejecting a "foreseeability test," and petitioners' request for *en banc* rehearing did not seek the adoption or application of a "foreseeability test," either. "[O]rdinarily, this Court does not decide questions not raised or resolved in the lower court," *Youakim v. Miller*, 425 U.S. 231, 234 (1976) (per curiam), and nothing contained in the petition suggests that this case is so exceptional that the general rule should not prevail here. *See Lawn v. United States*, 355 U.S. 339, 362-63 n.16 (1958). Medtronic's waiver of such a "foreseeability test" should end that inquiry.

To allow petitioners to inject such an issue now would deprive this Court of the benefit of the lower courts' refinement and resolution. In *Austin v. United States*, 509 U.S. 602 (1993), for example, the petitioner asked this Court to "establish a multifactor test for determining whether a forfeiture is constitutionally 'excessive.'" *Id.* at 622. This Court properly "decline[d] that invitation," on the ground that "[p]rudence dictates that we allow the lower courts to consider that question in the first instance." *Id.* at 622-23 (citing *Yee*, 503 U.S. at 538).

Moreover, by failing to raise its "foreseeability test" until now, petitioners have deprived respondents of the opportunity to make an appropriate record in response to that asserted test. *See United States v. United Foods, Inc.*, 533

U.S. 405, 416-17 (2001) ("The Government's failure to raise its argument in the Court of Appeals deprived respondent of the ability to address significant matters that might have been difficult points for the Government."). If this case is indeed "[o]ne of [m]any" presenting this issue, as petitioners claim (Pet. 12), then the Court would be well advised to await a later vehicle, where the issue was not waived, and where the question is better framed.

b. For another, petitioners' "foreseeability test" would swallow headlong this Court's much narrower foreseeability inquiry from *Festo*. In that case, the Court ruled that an amendment to a patent claim limitation carries with it a rebuttable presumption that all equivalents were surrendered, unless the patentee could rebut the presumption by showing, *inter alia*, that the claimed equivalent was "unforeseeable at the time of the amendment." *Festo*, 535 U.S. at 738. Petitioners are not shy about admitting their goal here: to expand the foreseeability inquiry to *all* doctrine-of-equivalents cases, even those "when prosecution history estoppel is not implicated." Pet. 24.

To require equivalents to be foreseeable "in all cases" (Pet. 25) would completely obviate the careful, measured approach that this Court took in *Festo*, where the foreseeability approach was limited to claim limitations that had been amended during prosecution of the patent. What is more, such an approach would be contrary to every doctrine-of-equivalents case decided by this Court, including *Festo*, *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997), *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950), and going all the way back to *Winans v. Denmead*, 56 U.S. (15 How.) 330 (1853). None of these cases supports, let alone even suggests, petitioners' sweeping "foreseeability" rule. Indeed, in *Graver Tank*, the asserted equivalent (silicates of manganese) to the claim limitation (silicates of calcium or magnesium) was actually disclosed in the patent (*see id.* at 613 (Black, J., dissenting)), so the use of manganese there

was not just "foreseeable," but actually foreseen. Yet the finding of equivalence in *Graver Tank* was upheld. Petitioners make no effort to square their sweeping new rule with over 150 years of this Court's precedents.

Even if this Court were otherwise poised to embrace petitioners' new and radical suggestion, which it should not, it assuredly should not do so in a case where the issue was never raised, and neither the Federal Circuit nor the trial court developed a factual record or made considered legal rulings on the issue.

3. A third reason for denying the petition lies in the nonfinal posture of the case in view of the Court of Appeals' decision to remand for a trial on the equivalence of petitioners' Vertex® product. Ordinarily, this Court will not grant review when a case is in such an interlocutory posture: "[B]ecause the Court of Appeals remanded the case, it is not yet ripe for review by this Court." *Bhd. of Locomotive Firemen v. Bangor & Aroostock R.R.*, 389 U.S. 327, 328 (1967) (per curiam) (citing *Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 257-58 (1916) ("The decree that was sought to be reviewed by certiorari at complainant's instance was not a final one, a fact that of itself alone furnished sufficient ground for the denial of the application . . . .")).

Petitioners are undoubtedly correct that there is no jurisdictional bar to review (Pet. 28), *see* 28 U.S.C. § 1254(1), but they do not offer any special or compelling reason for this Court to depart from the ordinary course and exercise review here.

4. Finally, the Court should decline to entertain the petition because the decision of the Court of Appeals was correct, and is not alleged to conflict with any decision of any other court of appeals, or of this Court. Rather, petitioners suggest only a generalized intra-circuit conflict in principle between cases they say evidence a "hard approach" and a "soft approach" to the doctrine of equivalents. Pet. 12-

21. Petitioners urge that this difference in approaches is exemplified by the different results in this case and in *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998).

Putting aside the fact that this Court rarely grants certiorari to resolve *intra*-circuit conflicts, which "are deemed an intramural matter to be resolved by the Court of Appeals itself," John M. Harlan, *Manning the Dikes*, 13 RECORD OF N.Y.C. BAR ASS'N 541, 552 (1958); *Davis v. United States*, 417 U.S. 333, 340 (1974), the differences in results in these cases were not a product of the application of different or conflicting legal rules, or, for that matter, jurisprudence of different "hardnesses" or "softnesses." Rather, the different results are simply a product of the differing facts and appellate records in those cases. Pet. App. 19a n.1. This demonstrates that the issue here is so factbound that certiorari would be both inappropriate and ineffective. *See, e.g., United States v. Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

In *Warner-Jenkinson*, this Court anticipated that vitiation rulings would be heavily fact-dependent: "Thus, under the particular facts of a case, . . . if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court . . . ." 520 U.S. at 39 n.8. *See also Graver Tank*, 339 U.S. at 609 ("[E]quivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case."). Thus, "the particular facts of a case" make all the difference in cases of alleged vitiation, not supposed "hard" or "soft" jurisprudential approaches.

Indeed, the Court of Appeals recognized the factbound nature of the "vitiation" inquiry in its opinion here, noting that vitiation has been found when, "on the facts or theories presented in a case, a limitation would be read completely out of the claim." Pet. App. 16a. That is why the Court of Appeals found its prior decision in *Tronzo* "factually

distinguishable." Pet. App. 19a. There, the patent contained independent claims drawn to artificial hip sockets having a "socket with no specific shape," and those claims were held invalid because of the absence of an adequate disclosure in the written description under 35 U.S.C. § 112, ¶ 1. Pet. App. 20a (citing *Tronzo*, 156 F.3d at 1158-60). Tronzo's efforts to then expand its other, not-invalidated claims for a prosthesis having "a generally conical outer surface," based on expert testimony that "*any* shape would be equivalent," were properly rejected by the Federal Circuit. Pet. App. 20a (citing *Tronzo*, 156 F.3d at 1160).

In this case, by contrast, there were no invalidated claims lacking an adequate description, and respondents' equivalence case did not attempt to recapture the territory of those invalidated claims by "propos[ing] that any shape would meet the 'spherically-shaped' limitation." In fact, respondents' expert presented a "particularized declaration" demonstrating his theory of equivalence using the function-way-result test (which this Court endorsed in *Warner-Jenkinson*, 520 U.S. at 39-40). He did not declare or even suggest that any shape would meet that test. *See* Pet. App. 20a-21a; C.A. App. 10367, 10539-40. (Petitioners are therefore incorrect to claim, as they do, that Respondents' expert in this case "testified that the specifically claimed shape was irrelevant." Pet. 15.) Also, as the Court of Appeals noted, "unlike the patent at issue in *Tronzo*, the written description and the '678 patent does not label other shapes as 'prior art' and 'inferior.'" Pet. App. 21a. In short, respondents' equivalence theory, unlike the theory advanced and rejected in *Tronzo*, was closely tethered to the claim language, in a way that did not "vitiate" any limitation in the patent. That makes this case not "strikingly similar" to *Tronzo* (Pet. 16), but strikingly different.

It is curious that, for all of petitioners' dependence on the alleged intra-circuit conflict in principle with the *Tronzo* decision, they fail to even cite two other cases, decided between *Tronzo* and this case, that further confirm how

understandable the different results in these cases are, based on the fact-and-context-dependent vitiation inquiry. In *Optical Disk Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1337 (Fed. Cir. 2000), the Court of Appeals held that "*Tronzo* does not stand for the proposition that a claim limitation describing a specific shape of a claimed structure cannot be infringed under the doctrine of equivalents by a differently shaped structure." And *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1361 (Fed. Cir. 2005) confirmed that what "particularly troubled" the *Tronzo* court was expert testimony that suggested that "'*any* shape would be equivalent to the conical limitation.'" An even more recent decision of the Court of Appeals further confirms, consistent with this Court's pronouncement in *Warner-Jenkinson*, that the vitiation inquiry is dependent on the "particular circumstances" of the claim language and the equivalence theory asserted in each case. *Foremost in Packaging Sys., Inc. v. Cold Chain Techs., Inc.*, No. 2006-1582, slip op. at 4 (Fed. Cir. May 2, 2007) (citing the decision below in this case).

The asserted differences between other Federal Circuit decisions, said by petitioners to evidence either a "'hard' approach to the doctrine of equivalents" (Pet. 17) or a "'soft' mode" (Pet. 19), are similarly understandable in this fashion. They, too, are fact- and context-dependent applications of the doctrine of equivalents, a doctrine which, "[i]t is true . . . renders the scope of patents less certain." *Festo*, 535 U.S. at 732. But that is a necessary part of the bargain, as this Court has observed, because "[i]f patents were always interpreted by their literal terms, their value would be greatly diminished." *Id.* at 731.

Petitioners' argument, stripped to its essence, is that courts should "adhere to the specific wording of a claim." Pet. 17; *see also* Pet. 23 (urging that the Court of Appeals here should have adhered to "the literal wording of the claim"). But that would effectively eliminate the doctrine of equivalents, contrary to this Court's pronouncement that

"[t]he scope of a patent is not limited to its literal terms." *Festo*, 535 U.S. at 732 (citing *Winans*, 56 U.S. (15 How.) at 347). Indeed, petitioners' complaint about the decision below and other allegedly "soft" approaches to the doctrine of equivalents would also seem to apply to a number of this Court's decisions applying the doctrine of equivalents to patent claims literally requiring a device to have a specified geometric shape. Most notable among these is *Winans* itself, which held that a claim requiring "a frustum of a cone" was infringed by non-conical structures (octagons and pyramids). 56 U.S. (15 How.) at 339-40. *See also Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 40-41 (1929) (upholding equivalence "[d]espite the changes in the" accused product from "the structure . . . disclosed" by the patent); *Union Paper-Bag Mach. Co. v. Murphy*, 97 U.S. 120, 123-24 (1877) (upholding equivalence between the patent's "cutter arranged to ascend and descend," and the accused serrated knife that "neither rises nor falls," yet cut paper that was moved over it); *Ives v. Hamilton*, 92 U.S. 426, 430-31 (1875) (upholding equivalence between a patent claim including a saw with curved guides and an accused "saw in which the guides are not curved"). Thus, the Court of Appeals' decision here—even if it could be categorized as being in a so-called "'soft' mode"—would still be in full accord with this Court's own precedents.

* * * *

In light of the factbound nature of this case, the poor question presented, the fact that petitioners' proposed "foreseeability test" has been newly minted for this late stage of litigation, the non-final posture of this case, the absence of any conflict (even an intra-circuit one), and the correctness of the decision below, the petition presents no colorable basis for review.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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